UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. GENERAL ELECTRIC COMPANY dba GE HEALTHCARE and GE OEC MEDICAL SYSTEMS, INC., corporations, and JOSEPH M. HOGAN, and PETER MCCABE, individuals, Defendants.	CONSENT DECREE OF PERMANENT INJUNCTION Case No. 2:07CV00017 B.S.J. Judge Bruce S. Jenkins

The United States of America, Plaintiff, by and through its attorneys, having filed a Complaint for Injunction against General Electric Company dba GE Healthcare and GE OEC Medical Systems, Inc., corporations, and Joseph M. Hogan, Senior Vice President, General Electric Company and President and Chief Executive Officer, GE Healthcare, and Peter McCabe, President and Chief Executive Officer GE Healthcare Surgery and President and Chief Executive Officer of GE OEC Medical Systems, Inc. (collectively, "Defendants");

Defendants, without admitting the allegations in the Complaint, and disclaiming any liability in connection therewith, having appeared, without contest and before any testimony having been taken, agreed to the entry of this Decree; and

Plaintiff having consented to entry of this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has subject matter jurisdiction over this action and personal jurisdiction over all parties pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332. Venue is proper in this district under 28 U.S.C. § 1391(b)&(c).

2. The Complaint for Injunction states a claim for relief under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act").

3. For purposes of this Decree, the following definitions shall apply:

A. "Defendants" shall refer to General Electric Company dba GE Healthcare, GE OEC Medical Systems, Inc., Joseph M. Hogan, and Peter McCabe.

B. "GE OEC Facilities" shall refer to the facilities at 384 and 640 Wright Brothers Drive, Salt Lake City, Utah, and 439 S. Union Street, Lawrence, Massachusetts.

C. "GE OEC Surgical Imaging Systems" shall refer to: (i) 9900 Elite C-Arm System, 9900 Elite NAV C-Arm System, 9800 C-Arm System, 2800 UroView System, 6800 MiniView System, Insta-Trak 3500 NAV System, ENTrak 2500 NAV System, and ConneCTstat; (ii) any components and accessories of any of those systems; and (iii) any other radiological image processing systems and image-intensified fluoroscopic x-ray systems manufactured, designed, processed, and/or packed at GE OEC Facilities. "GE OEC Surgical Imaging Systems" does not include the following products, including components and accessories thereof, which are not manufactured or designed by GE OEC Facilities: printers, uninterruptible power supplies, Medrad Injectors, IMI Nodeseekers, and similar devices.

D. "GE Healthcare" shall refer to General Electric Company dba GE Healthcare and GE OEC Medical Systems, Inc.

E. "Failure" shall include, but not be limited to, situations where a device does not meet its specifications and/or is defective within the meaning of 21 C.F.R. § 1003.2.

F. "Manufacturing" shall include designing, manufacturing, fabricating, assembling, processing, installing, labeling, sterilizing, relabeling, remanufacturing, repacking, and specification development.

4. Upon entry of this Decree, Defendants, and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, subject to the conditions set forth in paragraph 5, are permanently enjoined, pursuant to 21 U.S.C. § 332(a), from manufacturing, processing, reprocessing, packing, repacking, labeling, or distributing any GE OEC Surgical Imaging Systems at or from GE OEC Facilities, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, reprocess, pack, repack, label, hold, and distribute GE OEC Surgical Imaging Systems are established, operated, and administered in compliance with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, and this Decree;

B. Defendants select and retain, at Defendants' expense, an independent person or persons (the "Expert"), who is qualified by education, training, and experience to conduct inspections of all GE OEC Facilities, and to review procedures and methods for manufacturing, processing, reprocessing, packing, repacking, labeling, holding, distributing, and servicing GE OEC Surgical Imaging Systems, to determine whether Defendants' methods,

facilities, and controls are operated and administered in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree. The Expert shall be without personal or financial ties (other than a consulting agreement between the parties, or ownership of diversified mutual funds or similar investments that hold General Electric Company stock as no more than 10% of the funds' total assets) to Defendants or any officer or employee of General Electric Company or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within twenty (20) calendar days of retaining such Expert;

C. The Expert shall perform a comprehensive inspection of the GE OEC Facilities and their manner of operation and certify in writing to FDA: (1) that he or she has inspected the GE OEC Facilities, processes, and controls; and (2) whether Defendants' operations are, in the Expert's opinion, in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree. The Expert's report shall include, but not be limited to, the following:

i. An evaluation of the steps taken by Defendants to comply with 21 U.S.C. §§ 351(h) and 352(t)(2) and 21 C.F.R. Parts 803, 806 and 820;

ii. A detailed evaluation of GE OEC Facilities' current state of compliance with respect to the deviations set forth on FDA's Lists of Inspectional Observations issued to GE OEC Facilities since November 2004;

iii. An assessment of Defendants' procedures for their Corrective and Preventive Action ("CAPA") system, including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming products and other quality problems;

investigating the causes of nonconformities relating to products, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming products and other quality problems; verifying or validating corrective and preventive actions to ensure such actions are effective and do not adversely affect finished devices; implementing and recording changes in methods and procedures, as needed to correct and prevent quality problems; and conducting and documenting adequate failure investigations, as required by 21 C.F.R. § 820.100;

iv. An evaluation of the steps Defendants have taken to identify the root causes, or if not precisely known, the most probable root causes, for the failures and/or malfunctions in the GE OEC Surgical Imaging Systems (including accessories) and whether Defendants have implemented appropriate and effective measures to correct and prevent recurrence of those failures and/or malfunctions, including an evaluation of the adequacy and effectiveness of all recalls and/or field corrections undertaken to address any such failures and/or malfunctions;

v. An evaluation of Defendants' procedures for compliance with 21 C.F.R. Part 803 (adverse event reporting);

vi. An assessment of Defendants' compliance with 21 C.F.R. § 820.198(a) (receiving, reviewing, and evaluating complaints);

vii. An evaluation of whether Defendants have established and maintained adequate procedures for design controls, including design changes and design validation, to implement the appropriate and effective measures to correct and prevent recurrence

of identified root causes for the failures and/or malfunctions in the GE OEC Surgical Imaging Systems, as required by 21 C.F.R. § 820.30;

viii. An evaluation of whether Defendants have validated all quality system computer software for its intended use(s) according to an established protocol, as required by 21 C.F.R. § 820.70(i);

ix. An assessment of whether Defendants have established adequate procedures to ensure timely submission of reports of corrections and removals, as required by 21 C.F.R. Part 806; and

x. An evaluation of Defendants' instructions and procedures for performing and verifying that servicing meets specified requirements and whether Defendants analyze and process service reports in accordance with 21 C.F.R. § 820.200.

The Expert may choose to conduct separate inspections for the methods, processes, and controls for the GE OEC Surgical Imaging Systems, and provide separate certification reports for each device so long as the report also includes a certification for all of the methods, facilities, processes, and controls applicable to the manufacture of that device. The Expert shall submit his report(s) to FDA at the address(es) specified in paragraph 16.

D. Defendants report to FDA in writing the actions they have taken to ensure that the methods used in, and the facilities and controls used to manufacture, process, reprocess, pack, repack, label, hold, and distribute GE OEC Surgical Imaging Systems are operated and administered and will be continuously operated and administered in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree. This report shall

include an evaluation of the GE OEC Facilities' current state of compliance with respect to the deviations set forth on FDA's Lists of Inspectional Observations for GE OEC Facilities since November 2004. With the report, Defendants shall submit to FDA copies of all procedures for GE OEC Facilities related to compliance with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree that have been created or revised since August 29, 2006. For purposes of complying with this paragraph, Defendants may choose to prepare separate reports for the GE OEC Surgical Imaging Systems, provided that no more than three (3) reports are submitted to FDA related to the GE OEC Facilities in Salt Lake City, Utah.

E. Within thirty-five (35) calendar days of FDA's receipt of each report submitted by Defendants under paragraph 4.D., FDA may, in its discretion, commence an inspection of GE OEC Facilities to determine whether the requirements of this Decree have been met, and whether such facilities are otherwise operated in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree.

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 4.A-E. If Defendants have satisfied the criteria under paragraphs 4.A-E to resume operations with respect to one or more models of GE OEC Surgical Imaging Systems, but not all of the GE OEC Surgical Imaging Systems, FDA may issue the notice under this subparagraph to Defendants with respect to the GE OEC Surgical Imaging Systems satisfying the criteria set forth in this paragraph, notwithstanding the fact that other GE OEC Surgical Imaging Systems may not have satisfied such criteria. If FDA decides to commence an inspection pursuant to paragraph 4.E., FDA will determine whether to provide

this notification within forty-five (45) calendar days of concluding that inspection, and notify Defendants of its determination. If FDA decides not to commence an inspection pursuant to paragraph 4.E., FDA will determine whether to provide this notification within forty-five (45) calendar days of FDA's receipt of each report submitted by Defendants under paragraph 4.D., and notify Defendants of its determination.

G. Paragraph 4 does not apply to the ConneCTstat device.

5. The following conduct is not enjoined under paragraph 4 of this Decree but remains subject to paragraphs 7 and 9-11 below:

A. Defendants' distribution of GE OEC Surgical Imaging Systems for use in product demonstrations and in workshops, and in research laboratories, provided that the GE OEC Surgical Imaging Systems are labeled "For Demonstration Only - Not for Human Use" and the devices' imaging capability is demonstrated in a manner that does not use living human beings.

B. Defendants' manufacturing, processing, and distribution to testing laboratories of limited quantities of GE OEC Surgical Imaging Systems *solely* for the purpose of developing, testing, verifying, or validating design changes or modifications in accordance with 21 C.F.R. Part 820.

C. Defendants' manufacturing, processing, reprocessing, packing, installing, servicing, and distributing the disposable and commonly replaced components and accessories that are described in the GE Healthcare catalog titled "Surgery Disposables and Accessories" (copyright 2006; Reference No. LR-050090-01). Defendants shall immediately cease

distribution of any such disposable or commonly replaced component or accessory if the Expert or FDA notifies Defendants in writing that such components or accessories are not in compliance with the Act, its implementing regulations, or this Decree. Defendants may resume distribution of any such component or accessory under this paragraph if the Expert and FDA subsequently notify Defendants in writing that such components or accessories have been brought into compliance with the Act, its implementing regulations, and this Decree.

D. Any GE OEC Surgical Imaging System, including any component or accessory, that is packaged, held for sale, or distributed *solely* for the purpose of responding to a documented request or written order to: (i) provide routine service maintenance to GE OEC Surgical Imaging Systems that are in the possession of customers of GE Healthcare; (ii) replace components, parts, or accessories for such GE OEC Surgical Imaging Systems; or (iii) provide and install a loaner GE OEC Surgical Imaging System (not to exceed ninety (90) days) for a customer's GE Imaging System that is temporarily unavailable while it is being serviced; provided, however, that:

(a) Defendants shall send to customers a copy of all outstanding Recall Notification letters applicable to the customer's device upon providing such routine service maintenance or loaner; replacing components, parts, or accessories; or returning the customer's GE OEC Surgical Imaging System for which a loaner was previously furnished. However, if Defendants have provided a particular Recall Notification letter to a customer within the preceding sixty (60) days, Defendants may provide a written notice of the outstanding recall in

lieu of the Recall Notification letter and furnish a duplicate copy of the Recall Notification letter upon request; and

(b) Defendants shall maintain a record, and shall allow FDA access to such record upon request, of all such requests or orders and "ship to" records, which records must include the following:

(1) a detailed description of the requested order, service maintenance, or loaner request, including a description of the malfunctions or performance issues that gave rise to the request, if any;

(2) the date of any such request or order;

(3) the dates of service or loaner installation;

(4) the names, addresses, and telephone numbers of the persons/entities making any such request or order; and

(5) a description of the GE OEC Surgical Imaging System, components, parts, or accessories used to provide service maintenance or loaner GE OEC Surgical Imaging System.

(c) Defendants shall not manufacture any new GE OEC Surgical Imaging Systems to satisfy any service, replacement, or loaner request made under this paragraph.

(d) The ninety (90) day limitation and documentation requirements in paragraph 5.D. do not apply to loaner GE OEC Surgical Imaging Systems that have been continuously at the same customer site since October 10, 2006. If such a loaner device is

removed from the customer site, any future use of that device as a loaner by any customer, and any replacement or future loaner GE OEC Surgical Imaging Systems involving that customer site shall be subject to the loaner requirements of paragraph 5.D.

E. Any GE OEC Surgical Imaging Systems, including any component or accessory, manufactured, processed, packaged, labeled, held for sale, or introduced into interstate commerce *solely* for export from the United States, provided that all of the requirements of 21 U.S.C. § 801(e) have been satisfied with respect to any such device or component. For each GE OEC Surgical Imaging System or component distributed pursuant to this paragraph, Defendants shall maintain records evidencing Defendants' compliance with 21 U.S.C. § 801(e) for two years following such distribution.

F. Defendants' manufacturing, processing, packing, holding, or distributing devices *solely* for the purpose of conducting clinical trials in accordance with 21 C.F.R. Part 812, provided that Defendants comply with all applicable laws and regulations relating to the manufacture and distribution of investigational devices.

G. Defendants' manufacturing and distributing GE OEC Surgical Imaging Systems *solely* for the purpose of complying with the requirements of paragraph 6, provided that such GE OEC Surgical Imaging Systems comply with the requirements set forth in Defendants' corrective action plan(s) after approval by FDA under paragraph 6.

H. Defendants' installing sixteen (16) GE OEC Surgical Imaging Systems already in the possession of GE Healthcare customers that have been identified by Defendants in

correspondence dated December 20, 2006, where necessary for the safe operation and use of the device.

I. Defendants' distributing components of GE OEC Surgical Imaging Systems (except software upgrades and circuit board replacements) to third party service providers in response to orders for such components for their use in providing routine servicing and repair. At the time of any such distribution, Defendants shall send to the third party service provider a copy of all outstanding Recall Notification letters applicable to the device to be serviced or repaired and request that such Recall Notification letters be provided to the customer at the time the third party service provider provides routine servicing and repair.

J. Defendants' sale and distribution of any used radiological image processing systems and image-intensified fluoroscopic x-ray systems that were not manufactured or designed at GE OEC Facilities to a qualified refurbisher or remanufacturer for further processing.

K. Defendants' reinstallation of GE OEC Surgical Imaging Systems already in the possession of customers who request that their GE OEC Surgical Imaging System be moved from one location to another. Defendants will advise FDA in writing of their intent to conduct a reinstallation prior to commencing such reinstallation. Such notices shall include the name and address of the facility, and an explanation of why the reinstallation activity by Defendants is necessary for the safe operation and use of the device.

L. GE Capital Corporation's leasing and selling GE OEC Surgical Imaging Systems to those lessees currently in possession of those systems; provided that: (1) Defendants

provide to GE Capital Corporation's lessees copies of all applicable outstanding Recall Notification letters; (2) this subparagraph applies only to GE OEC Surgical Imaging Systems that GE Capital Corporation purchased, leased, and distributed prior to September 15, 2006; and (3) with respect to each such GE OEC Surgical Imaging System, if a lessee does not renew its lease or exercise its option to purchase its GE OEC Surgical Imaging System, that GE OEC Surgical Imaging System shall become subject to all of the restrictions in this Decree applicable to Defendants. Notwithstanding the foregoing, GE Capital Corporation may transfer ownership of any GE OEC Surgical Imaging System in its possession or custody to GE OEC Medical Systems, Inc.

6. A. No later than April 1, 2007, Defendants shall submit to FDA in writing a detailed Corrective Action Plan to bring the 9900 Elite C-Arm Systems, the 9900 Elite NAV C-Arm Systems, and the 9800 C-Arm Systems that are currently in use in the United States by physicians, hospitals, pharmacies, and other users/facilities and those that are currently being held at the GE Salt Lake City Facility into compliance with the Act, its implementing regulations, and this Decree. Defendants may choose to provide separate written Corrective Action Plans to FDA for these GE OEC Surgical Imaging Systems for purposes of complying with this paragraph. The written Corrective Action Plan(s) shall include, among other things:

i. identification of the root causes, or if not precisely known, the most probable root causes, of any and all failures and/or malfunctions with these GE OEC Surgical Imaging Systems;

ii. a description and supporting documentation for each upgrade, modification, and/or action necessary to correct these failures and/or malfunctions;

iii. the testing (protocols and data) conducted or to be conducted to verify and validate the upgrades and/or modifications;

iv. the projected dates on which Defendants will begin to implement and complete the Corrective Action(s);

v. the manner in which the upgrades and/or modifications will be made to these GE OEC Surgical Imaging Systems;

vi. whether these GE OEC Surgical Imaging Systems will be recalled to implement corrective actions; and

vii. a clear statement of whether Defendants' believe the proposed upgrades and/or modifications to the GE OEC Surgical Imaging Systems described in the Corrective Action Plan require premarket notification clearance by FDA, the reasons for that belief, and whether premarket notification clearance has been sought and obtained by Defendants.

B. Defendants shall not initiate any Corrective Action Plan until FDA has first provided Defendants with written authorization to do so. FDA shall respond in writing within forty-five (45) calendar days of FDA's receipt of Defendants' proposed Corrective Action Plan (or sixty (60) calendar days from receipt of each plan if more than one plan is submitted) and notify Defendants in writing whether the proposed plan(s) is (are) acceptable. If FDA finds any proposed plan unacceptable, it shall state in writing the reasons for finding the proposed plan

unacceptable, and Defendants shall submit a revised proposed Corrective Action Plan within twenty (20) calendar days of receipt of FDA's response. FDA's decision regarding the adequacy of Defendants' Corrective Action Plan(s) shall be final.

C. Defendants shall commence the implementation of the Corrective Action Plan(s) within thirty (30) calendar days of receiving FDA's written authorization. Defendants shall, beginning one month after the date on which implementation of the Corrective Action Plan(s) has begun, and continuing until its (their) completion, submit to FDA monthly written progress reports updating the status of the implementation of the Corrective Action Plan(s), including the number of devices that have not yet been upgraded and/or modified as set forth in the Plan(s). Defendants shall use their best efforts to locate all 9900 Elite C-Arm Systems, the 9900 Elite NAV C-Arm Systems, and the 9800 C-Arm Systems in use by health care professionals in the United States and to obtain the cooperation of such users to implement the corrective actions required by this paragraph.

7. Upon entry of this Decree, General Electric Company dba GE Healthcare, GE OEC Medical Systems, Inc., and Joseph M. Hogan, and Peter McCabe, for so long as such individuals are in positions of responsibility relating to any product subject to FDA jurisdiction at GE Healthcare or any of General Electric Company's franchisees, subsidiaries, affiliates, and/or "doing business as" entities, and each and all of Defendants' officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by

personal service or otherwise, are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly:

A. Causing the introduction or delivery for introduction into interstate commerce, of any GE OEC Surgical Imaging System that is adulterated within the meaning of 21 U.S.C. § 351(h), or misbranded within the meaning of 21 U.S.C. § 352(t)(2); and

B. Causing any GE OEC Surgical Imaging System that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(h), or misbranded within the meaning of 21 U.S.C. § 352(t)(2).

8. After Defendants receive the written notification from FDA pursuant to paragraph 4.F., Defendants shall retain an independent person or persons (the "Auditor") to conduct audit inspections of the operations at the GE OEC Facilities. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties, or ownership of diversified mutual funds or similar investments that hold General Electric Company stock as no more than 10% of the funds' total assets) to Defendants or any of General Electric Company's officers or employees or their immediate families, and may, if Defendants choose, be the same person or persons described as the Expert in paragraph 4.B. The inspections under this paragraph shall commence at each GE OEC Facility within one (1) year of Defendants' receipt of the notification described in paragraph 4.F. and shall be conducted at a frequency of no less than yearly intervals thereafter for a period of three (3) years, for a total of four (4) years.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") expressing in detail an opinion on whether Defendants are in compliance with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree, and identifying in detail any deviations from 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and this Decree ("Audit Report Observations"). As part of every Audit Report, except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations, and report in writing the actions taken to correct each item enumerated in the prior Audit Report(s), and which items have not been corrected, if any. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than thirty-five (35) calendar days after the date the audit inspections are completed. If any Audit Reports identify violations of 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806 and 820, and/or this Decree, FDA may, in its discretion, require that the auditing cycle be extended for a length of time not to exceed four (4) years. In addition, Defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within forty (40) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of an adverse Audit Report Observation will take longer than forty (40) calendar days, Defendants shall, within twenty (20)

calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification describing why the additional time is necessary. Any such Correction Schedule must be reviewed and approved by FDA in writing. Defendants may implement the Correction Schedule unless and until FDA notifies Defendants in writing that they should modify the Schedule. Defendants shall complete all corrections according to the approved Correction Schedule. Within forty (40) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observations. Within ten (10) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

9. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, analysis of samples, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its regulations, or that additional corrective actions are necessary to achieve compliance with this Decree or the Act, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions, including but not limited to, the following:

A. Cease the manufacture, processing, reprocessing, packing, repacking, labeling, holding, installing, servicing, or distribution of any or all GE OEC Surgical Imaging Systems located in or to be distributed into the United States;

B. Cease, directly or indirectly, importing any GE OEC Surgical Imaging Systems or any other radiological image processing systems or image-intensified fluoroscopic x-ray systems into the United States;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to the Decree with respect to GE OEC Surgical Imaging Systems located in or to be distributed in the United States;

D. Submit additional reports or information to FDA with respect to GE OEC Surgical Imaging Systems located in or to be distributed into the United States;

E. Recall, at GE Healthcare's sole expense, adulterated or misbranded GE OEC Surgical Imaging Systems manufactured, distributed, or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers in the United States;

F. Issue a safety alert or other notification with respect to GE OEC Surgical Imaging Systems located in the United States; and/or

G. Take any other corrective action(s) with respect to GE OEC Surgical Imaging Systems located in or to be distributed into the United States as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this Decree.

10. A. Any order issued by FDA pursuant to paragraph 9 shall be issued by the appropriate FDA District Director, and shall specify the deficiencies or violations giving rise to the order. Unless a different time frame is specified by FDA in its order, within fifteen (15)

calendar days after receiving an order pursuant to paragraph 9, Defendants shall notify FDA in writing either that (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decisions in writing. The written notice of affirmance or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and, if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order unless the Court reverses, modifies, or stays FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 19.

11. Any cessation of operations or other action described in paragraphs 9-10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree. The costs of FDA

inspections, sampling, testing, travel, review, and supervisory time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraphs 9-10 shall be borne by GE Healthcare at the rates specified in paragraph 13.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' GE OEC Facilities, and take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, reprocessing, packing, labeling, holding, and distribution of any and all devices. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374, and, upon Defendants' request and at Defendants' expense, with copies of any photographs or video recordings made. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. GE Healthcare shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by GE Healthcare at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $76.10 per hour and fraction thereof

per representative for inspection work; $91.18 per hour or fraction thereof per representative for analytical or review work; $0.445 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. FDA shall submit a reasonably detailed bill of costs to GE Healthcare at the address specified in paragraph 16. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them with responsibilities related to the manufacture and quality of GE OEC Surgical Imaging Systems (hereafter, collectively referred to as "Associated Persons"). In the event that GE Healthcare becomes associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall: (A) within fifteen (15) calendar days of such association, provide a copy of this Decree to such person(s) by personal service or certified mail (restricted delivery, return receipt requested), and (B) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree to all of Defendants' employees involved in the manufacture, processing, reprocessing, packing, storage, servicing, or distribution of GE OEC

Surgical Imaging Systems, by posting a copy of this Decree on GE Healthcare's intranet Web site in such a manner to ensure that it will be viewed by such employees, and shall prominently post a copy of this Decree in the employee common areas at all facilities where such employees are located. Defendants shall ensure that the Decree remains posted on GE Healthcare's intranet and in the employee common areas for no less than twelve (12) months. Within thirty-five (35) calendar days of the date of entry of this Decree, GE Healthcare shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who initially received a copy of this Decree and the manner of notification.

15. Defendants shall notify the District Director, FDA Denver District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, or affiliates, or any other change in the corporate structure of GE OEC Medical Systems, Inc. or the GE Healthcare division of General Electric Company or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

16. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the District Director, FDA Denver District Office, 6th & Kipling Street, Building 20, Denver Federal Center, Denver, Colorado 80225-0087, and, with respect to the Lawrence, Massachusetts facility, also to the District Director, New England District, One Montvale Ave., 4th Floor, Stoneham, Massachusetts 02180. All notifications, correspondence, and communications required to be sent to Defendants by the terms of this Decree shall be addressed to the Director of the Consent Decree Compliance Task Force at 384 Wright Brothers Drive, Salt Lake City, Utah 84116-2862.

17. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, GE Healthcare shall pay to the United States of America an amount not to exceed fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues and an additional amount not to exceed fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree. The amount of liquidated damages in this paragraph shall not exceed thirty-five million dollars ($35,000,000) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

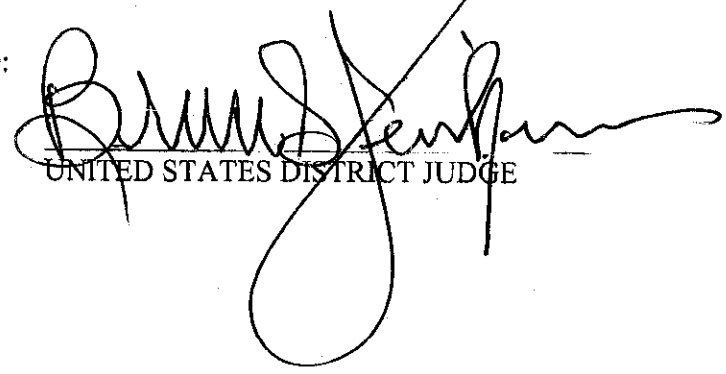
18. If the United States brings, and prevails in, a contempt action to enforce the terms of this Decree, GE Healthcare shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

19. All decisions specified in this Decree shall be vested in the sole discretion of FDA, and FDA's exercise of discretion shall be reviewed, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based exclusively upon the written record that was before FDA at the time of the decision. No discovery may be had by either party.

20. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained at the GE OEC Facilities a state of continuous compliance with the Act, its implementing regulations, and this Decree for the sixty (60) months preceding the petition, Plaintiff will not oppose such petition.

21. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

ENTERED:



UNITED STATES DISTRICT JUDGE

Date: 1/17/07

We hereby consent to the entry of the foregoing:

Respectfully submitted,

By Defendants:

JOSEPH M. HOGAN
individually and on behalf of
General Electric Company dba GE Healthcare as
Senior Vice President, General Electric Company
and President and Chief Executive Officer,
GE Healthcare

PETER MCCABE
individually and on behalf of
GE OEC Medical Systems, Inc. as
President and Chief Executive Officer
of GE Healthcare Surgery and as President and
Chief Executive Officer of GE OEC Medical
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