



December 06, 2006

PMA Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

SUBJECT: "REAL-TIME REVIEW REQUEST GRANTED"

**REAL-TIME Supplement to P020047 for MULTI-LINK VISION®
CORONARY STENT SYSTEM and MULTI-LINK MINI VISION®
CORONARY STENT SYSTEM**

To Whom It May Concern:

Abbott Vascular (formerly Guidant Vascular Intervention) is submitting this Real-Time Supplement to our approved Premarket Approval (PMA) application to place into effect two minor design modifications to the MULTI-LINK VISION® CORONARY STENT SYSTEM (CSS) and MULTI-LINK MINI VISION® CORONARY STENT SYSTEM (CSS). The Real-Time request was approved via facsimile and is attached to this cover letter.

Abbott Vascular is implementing a minor modification to the VISION® stent used on the MULTI-LINK MINI VISION® CSS (Small design, 2.0 – 3.0 mm diameters) and the MULTI-LINK VISION® CSS.

Abbott Vascular is also implementing this minor modification to the Medium design VISION® stent (3.5 and 4.0 mm diameters) used on the MULTI-LINK VISION® CSS for the same reason.

Additionally, Abbott Vascular is implementing a minor modification to the Medium Vision® stent used on the MULTI-LINK VISION® CSS.

SUBMITTED UNDER SEAL

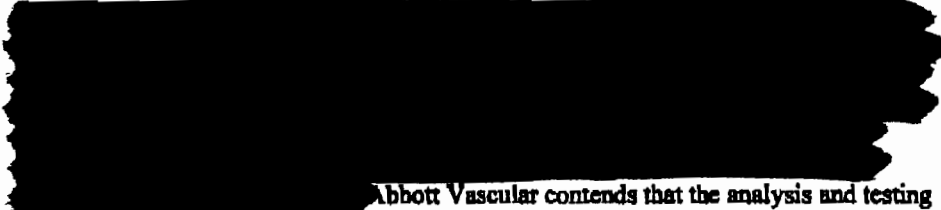


HIGHLY CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER

AB0727117

*Medtronic Vascular, Inc. et al. v. Advanced
Cardiovascular Systems, Inc. et al.
C.A. No. 08-1086 PJH (N.D. Cal.)*

The proposed W-crest modification and non-linear link shift to the ML VISION® CSS and ML MINI VISION® CSS stent designs are minor modifications.



Abbott Vascular contends that the analysis and testing performed adequately assessed the potential impact of the proposed design modifications. The results exhibit no impact to the safety or efficacy of the product and thus substantiate the implementation of the proposed changes.

In addition, Guidant Corporation has been recently acquired by Abbott, whereby the Vascular Intervention and Endovascular Solutions businesses are now wholly owned subsidiaries of Abbott Vascular. This occurred as a result of Guidant Corporation's merger agreement with Boston Scientific and Guidant Corporation's divestiture of Vascular Intervention and Endovascular Solutions assets to Abbott Laboratories prior to the merger with Boston Scientific. Over the next few months Abbott Vascular will transition the former Guidant filings over to the new corporate branding.

Abbott Vascular is proposing one of the following meeting dates to complete the Real-Time Review process: January 13, 2007 or January 19, 2007, preferably at 10:00 am PST. Please contact me to schedule a specific date, start time, and estimated duration. Abbott Vascular will provide a telephone conference number.

If you have any questions or require any additional information, please contact me at (951) 914-2797 or Marguerite Eras, Regulatory Affairs Manager, at (951) 914-2838. I may also be reached by fax at (951) 914-0339 or by e-mail at mblasco@guidant.com.

Sincerely,



Michael Blasco
Regulatory Affairs Associate

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AB0727118

Medtronic Vascular, Inc. et al. v. Advanced
Cardiovascular Systems, Inc. et al.
C.A. No. 08-1066 PJH (N.D. Cal.)

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1.0 Device Description

The MULTI-LINK VISION® and the MULTI-LINK MINI VISION® Coronary Stent Systems (CSS) are comprised of two main components: the Stent and the Delivery System. Since the design modifications detailed in this supplement pertain to the stent design, only a description of the VISION® stent design is provided.

1.1 Stent Overview

The MULTI-LINK (ML) MINI VISION® CSS and the MULTI-LINK (ML) VISION® CSS are balloon expandable stents.

There are two stent designs for the ML VISION® CSS: the *Small* VISION® stent design for the 2.75 mm and 3.0 mm diameters and the *Medium* VISION® stent design for the 3.5 mm and 4.0 mm diameters. Both stent designs are available in the 8 mm, 12 mm, 15 mm, 18 mm, 23 mm, and 28 mm lengths.

There is one stent design for the ML MINI VISION® CSS. It is identical in design and material to the *Small* VISION® stent used in the ML VISION® CSS (2.75 mm and 3.0 mm diameters). The ML MINI VISION® stent consists of diameters of 2.0 mm, 2.25 mm and 2.5 mm and lengths of 8 mm, 12 mm, 15 mm, 18 mm, 23 mm, and 28 mm.

2.0 Summary of Design Modifications

Abbott Vascular is implementing a minor modification to the VISION® stent used on the MULTI-LINK MINI VISION® CSS (Small design, 2.0 – 3.0 mm diameters) and the MULTI-LINK VISION® CSS [REDACTED]

[REDACTED] Abbott Vascular is also implementing this minor modification to the Medium design VISION® stent (3.5 and 4.0 mm diameters) used on the MULTI-LINK VISION® CSS for the same reason.

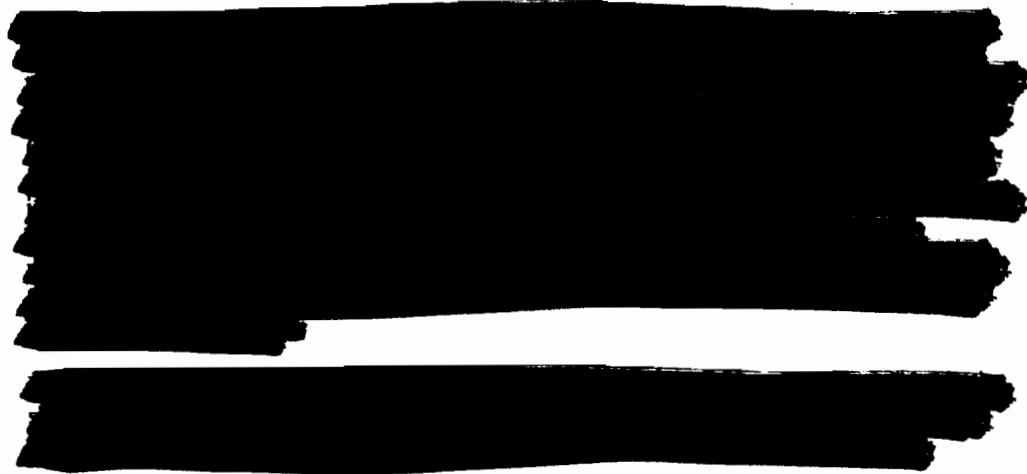
Additionally, Abbott Vascular is implementing a minor modification to the *Medium Vision®* stent used on the MULTI-LINK VISION® CSS [REDACTED]

[REDACTED] s of the W-crest modification and the NLL shift, as well as the stent diameters and sizes are given in Table 2.1.

Table 2.1 Summary of the product names and the stent sizes impacted by the proposed design modifications

Stent Diameter (mm)	Stent Length (mm)	Product Name	Stent Design	[REDACTED]	[REDACTED]
2.0	8, 12, 15, 18, 23, 28	MULTI-LINK MINI VISION®	Small	[REDACTED]	[REDACTED]
2.25	8, 12, 15, 18, 23, 28			[REDACTED]	[REDACTED]
2.50	8, 12, 15, 18, 23, 28			[REDACTED]	[REDACTED]
2.75	8, 12, 15, 18, 23, 28	MULTI-LINK VISION®	Small	[REDACTED]	[REDACTED]
3.0	8, 12, 15, 18, 23, 28			[REDACTED]	[REDACTED]
3.5	8, 12, 15, 18, 23, 28			[REDACTED]	[REDACTED]
4.0	8, 12, 15, 18, 23, 28		Medium	[REDACTED]	[REDACTED]

Both the modification to the W-crest and the shift of the NLL are within current specifications, considered minor and not expected to affect the performance of the product.



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C.A. No. 06-1086 PJH (N.D. Cal.)*