UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES,	)	
	)	
Plaintiff(s),	)	
	)	
vs.	)	Case No. 4:13-cv-00800-SRC
	)	
BIOMET, INC., et al.,	)	
	)	
Defendant(s).	)	

Memorandum and Order

Plaintiffs have moved to exclude evidence "arguing or insinuating that the FDA clearance of the M2a-Magnum indicates that the FDA believed" the device was safe for use. Doc. 241 at 13-14. In response, Biomet argues that the Court should exclude *all* evidence relating to FDA regulations and approval. Doc. 254 at 13. The Court finds that additional briefing on certain discrete issues will be helpful. Accordingly, the Court instructs the parties to brief the following issues:

1. Do medical device manufacturers have discretion to choose the route of FDA clearance? In other words, can the manufacturer choose to use the Premarket Approval process even if the product might qualify for 510(k) clearance?
2. Have any metal-on-metal hip implant devices obtained FDA approval via the Premarket Approval process since the 1976 enactment of the Medical Device Amendments? If so, which devices, and when?
3. Did any device identified as a substantially-equivalent "predicate device" in the M2a-Magnum's 510(k) clearance application complete the Premarket Approval process? If so, which devices, and when?

The Court orders the parties to submit briefs, not to exceed five pages and limited to the issues identified above, no later than 12:00 p.m. on Thursday, September 24, 2020.

Dated: September 22, 2020.

STEPHEN R. CLARK
UNITED STATES DISTRICT JUDGE