

IN THE CIRCUIT COURT OF THE TWELFTH JUDICIAL CIRCUIT
IN AND FOR SARASOTA COUNTY, FLORIDA

*IN RE: CONSOLIDATED BIOMET M2A HIP
REPLACEMENT CASES:*

*Consolidated Under:
2014 CA 001932 NC*

**ORDER ON PLAINTIFFS' MOTION
TO COMPEL PRODUCTION OF DOCUMENTS**

THIS MATTER, came to be heard on January 25, 2018 on the consolidated Plaintiffs' Motion to Compel Production of Documents filed on November 22, 2017 (the "Motion"), and having reviewed the Motion and exhibits attached thereto, Defendants' Response Brief in Opposition to the Motion and exhibit attached thereto (filed on January 18, 2018), having heard argument of counsel for the parties, and having been fully advised on the issues, it is hereby

ORDERED and ADJUDGED that:

1. The Motion is **GRANTED in Part and DENIED in Part**.
2. Given the nature of the consolidated Plaintiffs' Claims for M2a metal on metal hips manufactured at the "Warsaw North Campus", the Court finds that the FDA's November 22, 2016 "Form 483" observations relating to the Biomet Defendants "Warsaw North Campus" and Zimmer Biomet's December 21, 2016 Response to the FDA's observations are within the scope of discoverable information under Rule 1.280(b).
3. Consistent with the Court's finding, the Court **GRANTS** Plaintiffs' Motion and **COMPELS** the Biomet Defendants to produce all documents requested by Plaintiffs in Requests One through Three and Five through Eight, identified below:

Request #1:

The full, unredacted FDA Form 483 (dated Nov. 22, 2016) plus any attachments, exhibits and enclosures supplementing this document.

Request #2:

The full, unredacted Zimmer Biomet Response to FDA 483 (dated Dec. 21, 2016) plus any attachments, exhibits, and enclosures supplementing this document and any updates issued to this response since December 21, 2016.

Request #3:

The full March 31, 2016 Corporate Complaints Process Audit report Completed by the Corporate Audit Team which, as explained by Zimmer Biomet in its Response to FDA 483, "focused on the Warsaw North complaint handling process and identified 6 major and 2 minor observations which were addressed as part of the post market surveillance remediation program CAPAs."

Request #5:

The full June 7, 2016 Corporate General QMS Audit completed by the Corporate Audit Team which "identified 15 major and 5 minor observations which were addressed using the CAPA system."

Request #6:

The summary of the Quality Excellence Plan which was provided to the FDA DET-DO on February 10, 2016.

Request #7:

All Corrective Action, Preventative Action, and/or CAPA reports discussed in Zimmer Biomet's Dec. 21, 2016 Response to FDA 483.

Request #8:

All HHE and HHED reports discussed in Zimmer Biomet's Dec. 21, 2016 Response to FDA 483, including any HHEs and HHEDs discussed in response to Observation 5A.

4. The Court further **GRANTS** Plaintiffs' Motion and **COMPELS** Defendants to produce the "April 13, 2016 Corporate Design Controls Audit report of the Warsaw North Campus" requested by Plaintiffs in Request Four, identified below:

Request #4:

The full April 13, 2016 Corporate Design Controls Audit report of the Warsaw North campus which "was requested to evaluate the applicability of the lessons learned from the Zimmer Warsaw West Campus design control 483 observations" and which "identified 4 critical and 15 major observations which resulted in the establishment of the design controls remediation program CAPAs."

5. The Court **DENIES** Plaintiffs' Motion to the extent that Request Four, identified above, requests the production of Zimmer Biomet's analyses or review of the "Zimmer Warsaw West Campus." Defendants' counsel confirmed that that the products at issue in this Matter were not manufactured at that facility. Plaintiffs' counsel confirmed that the request was intended solely for the production of documents pertaining to the facility in which the products at issue were manufactured.
6. Defendants are Ordered to produce to Plaintiffs the documents identified in Paragraphs Three and Four of this Order within Twenty-One (21) days of the entry of this Order

7.

~~_____~~
~~_____~~
~~_____~~

DONE AND ORDERED in Sarasota, Sarasota County, Florida this _____ day of _____, 2018.

ORIGINAL SIGNED

JAN 31 2018

HUNTER W. CARROLL
CIRCUIT JUDGE

HUNTER W. CARROLL
CIRCUIT JUDGE

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