BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: MDL NO. 3044

PRODUCTS LIABILITY LITIGATION

RESPONSE OF DEFENDANTS EXACTECH, INC. AND EXACTECH U.S., INC. TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

Plaintiffs involved in related product liability claims against Exactech, Inc. and its subsidiary Exactech U.S., Inc. have moved pursuant to 28 U.S.C. § 1407 to transfer the actions to the United States District Court for the Eastern District of New York for coordinated and consolidated pretrial proceedings. (Dkt. 1) As detailed below, Exactech, Inc. and Exactech U.S., Inc. (collectively, the "Exactech Defendants") agree that the cases should be transferred for coordination and consolidation of pretrial proceedings pursuant to section 1407. However, the Exactech Defendants propose centralization in the Southern District of New York (Judge Paul. A. Engelmayer) or the Eastern District of Louisiana (Judge Sarah S. Vance). This response will attempt to minimize repetition with plaintiffs' motion and instead provide additional information to the Panel in support of centralization before the Exactech Defendants' proposed district courts and judges.

I. FACTS

A. Parties and Background

Exactech, Inc. ("Exactech" or "the company") manufactures medical devices, including knee, hip, and ankle replacement components.

In summer 2021, Exactech issued two product alerts. First, on June 28, 2021, Exactech published a product safety alert regarding the clinical performance of the polyethylene used in its

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hip systems ("Connexion GXL"). Second, on August 31, 2021, Exactech initiated a recall related to the vacuum-bag packaging of polyethylene inserts used in its knee and ankle devices.

Plaintiffs identified in the petition are patients who underwent knee- or hip-replacement surgery, in which Exactech devices were implanted; since the petition was filed, at least one patient who underwent ankle-replacement surgery with an Exactech device has filed a potential tag-along action. Plaintiffs generally claim that their devices prematurely failed or caused damage, requiring the devices to be removed and causing personal injuries. They allege product-liability and related claims. Additional similar actions have been filed in multiple state courts.

Exactech, Inc. designed, manufactured, labeled, and sold the subject devices and is the proper defendant in these matters,

Plaintiffs' motion also mentions two other entities: Osteon Holdings, Inc. and TPG Capital. These entities are merely holding companies with no involvement in designing, manufacturing or selling the products. Osteon Holdings is Exactech, Inc.'s immediate corporate parent. TPG Capital is a division of TPG, Inc., a publicly-traded corporation that indirectly owns the shares of Osteon.

B. The Products At Issue

1. Knee Components

A knee replacement generally consists of four components: a femoral component, tibial tray, a patellar component, and a polyethylene tibial insert, which are implanted in the configuration shown in the diagram below:



Exactech has marketed three generations of knee components under the brands

Optetrak®, Optetrak Logic®, and Truliant®, all of which were cleared by the U.S. Food & Drug

Administration ("FDA") under Section 510(k) of the Food, Drug and Cosmetic Act. The

components for each system have undergone substantial testing in both the pre- and post-launch

phases of the devices to validate their safety and effectiveness for their intended uses. The

company has quality system procedures in place to control all aspects of the design and

manufacturing process, as well as procedures for the handling, storage, preservation, and

delivery of products.

Exactech components are packaged individually in separate bags. The company's packaging design specifications and drawings for the polyethylene insert packaging called for inner vacuum bags composed of layers of LDPE (low density polyethylene), Polyamide (Nylon), and EVOH (ethylene vinyl alcohol). The bags were sold to Exactech by an outside supplier. In July 2021, during review of packaging material certifications from its supplier, Exactech discovered that some of the inner bags used to package the polyethylene inserts lacked an EVOH layer, which could potentially elevate oxygen transmission to the polyethylene inserts inside the package.

Upon discovering the absence of an EVOH layer in some of its inner bags, Exactech studied and evaluated the risk associated with that absence. Notably, while some bags did not

contain the EVOH layer, all bags contained the Nylon and LDPE layers, which provided an oxygen barrier, even in the absence of EVOH. In other words, all bags at issue—even with the non-conformity—contained protections against oxygen transmission to the contents of the bag.

Exactech also commissioned extensive testing—performed both in house and in an independent laboratory by world-renowned polymer experts—to further evaluate the risk presented by non-conforming bags. The testing established that polyethylene inserts packaged without the EVOH layer that are implanted within five years of manufacture should perform similarly to those packed in Nylon/LDPE bags with EVOH. In addition to testing, the company thoroughly reviewed other sources (e.g., clinical studies, scientific literature, and reports) to assess the safety and performance of its knee components and found that the overall rate for surgery to replace the polyethylene components in all Exactech knee systems was very low (less than 1%).

Notwithstanding the results of its testing, Exactech initiated a recall on August 31, 2021. https://www.exac.com/medical-professionals/recall-information/ (last accessed on June 20, 2022). At that time, the company asked sales agents to immediately return knee and ankle (see below) polyethylene devices on the shelf that were packaged in non-conforming bags that were labeled with an eight-year shelf life. For the next several months, Exactech worked at length with the FDA on the details of the second phase of the recall, which culminated in an expanded recall announced on February 8, 2022.

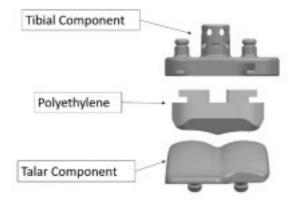
Information about the recall is set forth in detail at https://www.exac.com/medical-professionals/recall-information/. There, patients can see a list of all recalled products and look up the serial number of their implant to determine if it falls within the parameters of the recall. They are directed to key phone numbers and helplines, hand-outs, letters to patients and

surgeons, and a page of Frequently Asked Questions. The website also contains pages dedicated to surgeons and healthcare professionals. For patients who were implanted with polyethylene devices packaged in bags without an EVOH layer, Exactech asked surgeons to closely monitor patients with new or worsening pain, inability to bear weight, grinding or other noise, swelling, or instability, and to consider performing X-rays to further evaluate the device. For patients who exhibit premature polyethylene wear, surgeons should consider revision surgery based on their clinical judgment.

2. Ankle Components

The recall also applies to Exactech's ankle arthroplasty system—the Vantage Total

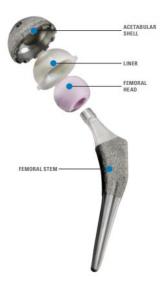
Ankle. As with the knee system, the Vantage ankle system incorporates a polyethylene insert:



Some lots of these inserts were also packaged bags without an EVOH layer. The studies and analyses described above for Exactech knee components applied to the ankle polyethylene, as well. Also, as with knees, Exactech painstakingly reviewed other sources (e.g., clinical studies, scientific literature, and reports) to assess the safety and performance of its ankle components and found that the overall revision rate associated with polyethylene wear in the Vantage was again very low (less than 1%). Nevertheless, Exactech has recalled its ankle polyethylene insert on the same timeline and in the same manner as the knee devices.

3. Hip Components

A hip component generally has four components: an acetabular shell, polyethylene liner, femoral head, and femoral stem, which are implanted in the configuration shown below:



In June 2021, Exactech issued a Product Safety Alert and "Dear Health Care Professional" letter regarding the performance of the Connexion GXL polyethylene liner. The alert reported that Exactech had observed early linear wear and volumetric wear of the liner in a small percentage (0.118%) of patients who were 3-6 years out from their total hip replacement. As noted in the alert, the phenomenon appears to occur when the relative implant position of the acetabular and femoral components results in edge loading of the femoral head on the liner. It also appears to be more common in certain surgical approaches (i.e., direct anterior approach), in patients with higher activity levels, and in patients who have been implanted with larger femoral heads and in which the thinnest available acetabular liner was used.

Based on this information, Exactech recommended that surgeons ask patients who are less than six years from their implant surgery and who have not been seen in more than 12 months to return to the office or clinic for a routine clinical exam and x-rays to assess relative

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alignment of the components and edge loading. For patients with edge loading components, early asymmetric polyethylene wear, and early signs of osteolysis, Exactech recommended that surgeons consider replacing the GXL liner with its latest generation Vitamin E liner.

C. Factors Affecting Performance of an Implant

Exactech is dedicated to implementing the product alerts and recall described above for the safety of patients using these devices. Yet, no singular joint replacement design available today can eliminate the possibility of component mechanical failure and ensure infinite functional life. These limitations are well known in the medical device, orthopedic, and regulatory communities. The American Academy of Orthopaedic Surgeons ("AAOS") aptly states:

Whether [total joint arthroplasty] implants can realistically be guaranteed from 5 years—let alone 20 years—is also questionable. Catastrophic implant failures can mechanically occur in the absence of a design or manufacturing flaw.

 $\underline{https://web.archive.org/web/20150907022434/http:/www.aaos.org/news/aaosnow/mar14/research5.asp.}$

Many variables can affect the overall clinical performance to an arthroplasty construct after it is implanted into a patient. For example, surgical factors (such as component sizing, alignment, ligament and soft tissue balancing, cementation technique, bone cutting and bone preparation techniques, and damage to critical ligaments and soft tissues) impact the durability of an implant. Moreover, while joint arthroplasty is largely successful in attaining the clinical goals of surgeons and patients, no joint replacement can be expected to withstand activity levels and loads similar to that of normal healthy bone for the lifetime of the patient. It is understood that knee replacements will not be as strong, reliable, or durable as natural human bone and tissue. They have a limited life expectancy and may need to be replaced at some time in the future. Moreover, patient factors, such as age, body mass index, bone quality, nutrition, and activity

level, are critical to the long-term success of a total joint replacement. These non-implant factors will require evaluation in each of the cases proposed for centralization.

D. <u>Complaints In The Involved Actions</u>

In the actions involved in this proposed MDL, plaintiffs allege that they received Exactech devices that experienced premature wear or failure due to product defects, that they suffered resulting personal injuries, and that they either have had or soon will have revision surgery to remove the devices. Of the cases identified in plaintiffs' § 1407 motion, 22 involve knee implants and five involve hip implants. (*See* Dkt. 1-2, Schedule of Actions) Notices of six related cases, all involving knee implants, have been filed. Exactech is aware of 11 additional potential tag-along cases involving knee implants and one involving a hip implant. The original, related and potential tag-along cases are brought by 19 different plaintiffs' firms or groups of firms. All of these actions are at an early stage, with all but one filed in 2022 and none yet the subject of significant document production; no depositions have yet been taken.

The complaints all revolve around allegedly excessive and premature wear of polyethylene parts in implanted joint replacement devices, which allegedly led to injuries such as osteolysis and the need for further surgery to remove parts of the devices. Plaintiffs typically allege that the problems were caused by oxidation of the polyethylene liners, which in turn was caused by alleged negligence and product defects, including alleged manufacturing, design, and warning defects.

II. <u>ARGUMENT</u>

The Exactech Defendants disagree with plaintiffs on many issues central to the merits of their claims. However, as outlined more fully below, the Exactech Defendants agree that plaintiffs' actions present common questions of fact and centralization will serve the parties' and

witnesses' convenience and promote the just and efficient conduct of this litigation. See 28 U.S.C. § 1407(a).

A. The Cases Involve Common Questions of Fact.

Exactech generally agrees with plaintiffs' explanation at Dkt. 1-1, pages 12-15¹ that the cases involve common questions of fact with respect to the design, manufacturing and labeling of the devices at issue. While Exactech disagrees with many of plaintiffs' core allegations, the question of whether those allegations are accurate is common to each of the actions proposed for centralization.

Section 1407 requires that the cases to be centralized raise "one or more common questions of fact." It does not require "a complete identity or even majority of common factual issues as a prerequisite to transfer." *In re Ins. Brokerage Antitrust Litig.*, 360 F. Supp. 2d 1371, 1372 (J.P.M.L. 2005). The cases here generally involve joint loosening, pain, and revision surgery, and factually similar allegations of defective manufacture, defective design, failure to warn, misrepresentation, and breach of warranty. The Panel has previously centralized joint-implant cases with similar claims and allegations. *See, e.g., In re: Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 802 F. Supp. 2d 1374, 1376 (J.P.M.L. 2011) (centralizing based on common factual issues arising from allegations that the affected knee implants "are prone to premature loosening causing affected individuals pain and loss of movement, and often forcing them to undergo revision surgery."); *In re: Stryker Rejuvenate and ABG II Hip Implant Prods. Liab. Litig.*, 949 F. Supp. 2d 1378, 1379 (J.P.M.L. 2013) (mem.) ("The actions share factual questions

¹ Exactech disagrees with the paragraph on page 15 of plaintiffs' motion, beginning "Moreover, intertwined with these facts, is the timing of corporate changes." (Dkt. 1-1, p. 15) Exactech, Inc. and Exactech U.S., Inc. are separately incorporated. The complaints do not allege any plausible basis for liability of corporate affiliates. But putting that incorrect paragraph of plaintiffs' motion aside, there are numerous common questions related to plaintiffs' substantive allegations, as detailed in plaintiffs' motion and in this response.

concerning design, manufacture, marketing and performance of Stryker's recalled Stryker Rejuvenate and ABG II modular-neck stems. Centralization will eliminate duplicative discovery, prevent inconsistent pretrial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary."); *In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358 1360 (J.P.M.L. 2011) ("The actions share factual questions as to whether DePuy's Pinnacle Acetabular Cup System, a device used in hip replacement surgery, was defectively designed and/or manufactured, and whether defendants failed to provide adequate warnings concerning the device.").

The actions here involve the same kinds of common factual issues, in addition to common issues unique to these cases. To name a few, the common factual issues include: the physical and chemical effects of oxygen on polyethylene liners during shelf storage, including how fast and under what conditions those effects occur; the effects of oxidized polyethylene liners in the human body, including the effects of polyethylene particles alleged to result from oxidation; and, more generally, the overall safety profile and clinical performance of the Exactech products at issue.

Obviously not *all* issues in these cases are common. However, the presence of case-specific issues, such as each plaintiff's unique medical history and individual causation, does not undermine the benefits of transfer and coordination for these cases. The "presence of some individual factual issues is true of most products liability cases and, in particular medical device cases," and "[s]uch differences are not an impediment to centralization where there are substantial factual issues in common." *In re Zimmer M/L Taper Hip Prosthesis or M/L Taper Hip Prosthesis With Kinectiv Technology and Versys Femoral Head Prods. Liab. Litig.* 340 F. Supp. 3d 1379, 1381 (J.P.M.L. 2018).

B. <u>Coordination of These Cases For Pretrial Proceedings Would Serve The Convenience of the Parties And Witnesses.</u>

Exactech also agrees that coordination of the Optetrak, Truliant, Vantage, and Connexion GXL cases will serve the convenience of the parties and witnesses. (Dkt. 1-1, Motion pp. 15-16)

Transfer is appropriate where the Panel determines that a coordinated proceeding "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of the litigation." 28 U.S.C. § 1407(a). That standard is met when centralization "will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary." *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 138 F. Supp. 3d 1381, 1382 (J.P.M.L. 2015). Here, the Exactech Defendants believe that centralization is appropriate, anticipating that the parties will work together to craft solutions that avoid duplication and conserve judicial resources.

The common issues identified in Part A above are likely to arise in most every involved case. The same groups of employees are likely to have relevant information with respect to knee implants, to hip implants, or to ankle implants, and other employees are likely to have relevant information applicable to all of the knee, hip, and ankle implants at issue (e.g., material science, manufacturing, risk management, quality, complaint reporting, and regulatory).

The Exactech Defendants are agreeing to coordination with the expectation the Exactech's employees, corporate representatives, and experts will not be subject to multiple depositions. Preparing for and giving repetitive depositions would be a severe drain on the time of employees – both percipient witnesses and corporate representatives. The numerous business days needed for multiple witnesses to prepare, give, and in some cases travel to depositions would disrupt them from doing their day jobs and affect Exactech's ability to run its business. Similarly, the parties' expert witnesses would need to write reports and prepare for and give

duplicative depositions in each of those same dozens of cases, which can be avoided through centralization.

Moreover, transfer and coordination will "conserve the resources of parties, their counsel, and the judiciary." *In re Zofran, supra,* 138 F. Supp. 3d at 1832. Absent coordination, Exactech will likely be required to respond to overlapping but non-identical document demands in 30 or more different cases. The issue is not merely producing documents. Responding to document demands, negotiating with opposing counsel over the entry of protective orders in each case, and the inevitable discovery disputes, are themselves time-consuming, inefficient and expensive. And in major litigation, document demands predictably lead to motion practice. If the cases remain pending before different judges for discovery, the same issues are likely to be litigated in numerous motions to compel and motions for protective orders in different cases, with inconsistent rulings and needless burden on the federal judiciary. With 30 cases filed at roughly the same time and many of the same witnesses in each case, scheduling conflicts between different courts are also likely.

Centralization will also eliminate the risk of inconsistent pretrial rulings on discovery and other pretrial matters. *See, e.g., In re Pineapple Antitrust Litig.,* 342 F. Supp. 2d 1348, 1349 (J.P.M.L. 2004) (consolidating cases to "prevent inconsistent pretrial rulings", eliminate duplicative discovery and conserve resources). As detailed in Part I.D and II.A, these actions involve a multitude of overlapping factual allegations and legal claims. For example, nearly all of the cases include claims – which Exactech denies – that Exactech knew or should have known of a problem long before the recall. Nearly all of the cases present engineering and chemistry questions about the rate and effect of oxidation of the polyethylene liners, whether oxidation presents a significant risk to the patient, and more – all of which will be the subject of expert

testimony and potentially-inconsistent Rule 702 rulings. Allowing the cases to proceed separately through pre-trial proceedings would create a significant risk of inconsistent pretrial rulings on numerous issues that could lead to inconsistent outcomes. Centralization would prevent such inconsistency. *See, e.g., In re Digital Advert. Antitrust Litig.,* 555 F. Supp. 3d 1372, (J.P.M.L. 2021) ("Centralization will promote the just and efficient conduct of the litigation by eliminating duplicative discovery and avoiding the risk of inconsistent rulings on pretrial matters, particularly on discovery disputes, *Daubert* issues, and dispositive motions.").

The cases involving the various knee, hip, and ankle devices should be transferred to a single court and judge for coordinated pretrial proceedings. Transfer will be particularly helpful here because these actions are still in the very early stages. As noted above, 26 of the 27 cases were filed this year. None of these cases has progressed beyond early discovery, allowing for the development of an efficient litigation and discovery plan and coordination with state cases at the outset.

All told, Exactech agrees that these cases should be centralized pursuant to § 1407.

C. The Panel Should Centralize the MDL Proceeding in the Southern District of New York Or, in the Alternative, the Eastern District of Louisiana, to Promote the Just and Efficient Conduct of this Litigation.

1. Southern District of New York

The Southern District of New York has considerable experience handling MDL proceedings (including product liability medical device cases)² and would be a good choice here.

² See generally,

https://www.jpml.uscourts.gov/sites/jpml/files/JPML%20FY%202021%20Report%20Cumulative%20Terminated%20MDLs.pdf, at 8-12 (identifying previously terminated MDL proceedings, including those in Southern District of New York);

https://www.jpml.uscourts.gov/sites/jpml/files/Pending MDL Dockets By District-Jul-15-2022.pdf, at 3-4 (identifying currently pending MDL proceedings in Southern District of New York).

There are currently eight actions pending in the district (six current member actions and two potential tag-alongs Exactech is aware of). One of them, *Perez v. Exactech, et al.*, No. 1:22-cv-05863-PAE, was recently assigned to Judge Paul A. Engelmayer, a jurist who oversaw another medical product liability MDL proceeding. *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)* (MDL No. 2767). Plaintiffs acknowledge that the Southern District of New York could also be considered. Dkt. 1-1. Motion at 18.

Plaintiffs suggest that the cases be assigned to Judge Kiyo A. Matsumoto of the Brooklyn Division of the Eastern District of New York, who currently presides over 12 actions. Dkt. 1-1, Motion at 17-19. We note that since the filing of the MDL petition, seven actions have been filed in the Eastern District of New York. Under these circumstances, simply assigning the litigation to that district on the basis of the number of cases pending there would provide plaintiffs with an undue advantage to steer the venue selection in favor of a particular district. Plaintiffs, not defendants, can unilaterally decide which of their cases to file when and where (subject to venue and jurisdictional rules).

2. Eastern District of Louisiana

In the alternative, Judge Sarah S. Vance of the Eastern District of Louisiana, former Chair of this Panel, would also be a good choice here. Judge Vance presides over the *Billups* action pending in that district.⁴ Judge Vance and the district have vast experience with MDL

³ Last month, Judge Engelmayer was assigned a new (non-product liability) MDL proceeding. *IN RE: ONE Apus Container Ship Incident on November 30, 2020* (MDL No. 3028). Nevertheless, we note Judge Engelmayer's prior medical related product liability MDL experience for consideration should docket conditions and availability permit a new MDL assignment.

⁴ Moreover, there is another case alleging similar allegations arising from the same medical device pending in Louisiana state court. Bonin v. Exactech, et al. [Case No.]

proceedings. In particular, Judge Vance has presided over three prior MDL proceedings⁵, but is not currently assigned to an MDL proceeding. The district has served as the transferee court for several product liability MDL proceedings.⁶ Moreover, Exactech is headquartered in the Southeastern United States (Gainesville, Florida), thus making the Eastern District of Louisiana a venue more regionally proximate to the location of the witnesses and documents. Accordingly, this litigation affords the Panel with the opportunity to assign a jurist with considerable experience with the conduct of MDL proceedings in a district well-versed in managing such proceedings – and, in particular, product liability MDLs.⁷

III. CONCLUSION

Exactech respectfully requests the Panel to transfer all actions listed in plaintiffs'
Schedule of Actions (Dkt. 1-2) and all subsequently-filed related actions to a single court for

⁵ In re Ford Motor Co. Vehicle Paint Prods. Lab. Litig. (MDL No. 1063); In re Educational Testing Service PLT 7-12 Test Scoring Litig. (MDL No. 1643); In re Pool Products Distribution Market Antitrust Litig. (MDL No. 2328).

⁶ See generally https://www.jpml.uscourts.gov/sites/jpml/files/JPML%20FY%202021%20Report%20Cumulative%20Terminated%20MDLs.pdf, at 22-23 (identifying previously terminated MDL proceedings in the Eastern District of Louisiana); https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-Jul-15-2022.pdf, at 2 (identifying several product liability MDL proceedings in the Eastern District of Louisiana).

⁷ Although the latest U.S. Court statistics reflect that, as of March 31, 2022, the Eastern District of Louisiana had 20,724 pending actions, with 1,727 per judgeship, the vast majority of those actions are in two MDL proceedings, including Xarelto (which is winding down). *See* https://www.uscourts.gov/sites/default/files/fcms_na_distprofile0331.2022.pdf (providing statistical data as of March 31, 2022 as to number of actions within district and per judgeship); https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-April-15-2022.pdf (as of April 15, 2022, there were 18,209 actions in the district subsumed within five MDL proceedings, including Xarelto, Chinese Drywall, and Deepwater Horizon, which are winding down). With only approximately 2,500 actions pending in the district outside of MDL proceedings, it appears at the district has the capacity for a new MDL proceeding, and none of the pending MDL proceedings are assigned to Judge Vance.

coordinated and consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. If an MDL is established, the Panel should centralize the action in the Southern District of New York (Judge Paul A. Engelmayer) or in the Eastern District of Louisiana (Judge Sarah S. Vance).

Dated: July 20, 2022 Respectfully submitted,

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY

MDL NO. 3044

LITIGATION

PROOF OF SERVICE

I hereby certify that counsel for all parties are registered for electronic service by the Court's CM/ECF system; that the foregoing RESPONSE OF DEFENDANTS EXACTECH, INC. AND EXACTECH U.S., INC. TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK is being filed by CM/ECF; and that all parties are being served electronically by the CM/ECF system's notice of electronic filing.

Dated: July 20, 2022 Respectfully submitted,

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