CITIZEN PETITION

Jeff and Janet Connell, by and through their legal representative, Eric S. Rossman of ROSSMAN LAW GROUP, PLLC.

February 28, 2019

The undersigned submits this petition as the legal representative for Jeff and Janet Connell, under the provisions of the Biomaterials Access Assurance Act, codified at 21 U.S.C. § 1601, *et. seq.*, and specifically pursuant to 21 U.S.C. § 1604(b)(3) which allows a claimant to petition the Secretary of Health and Human Services to make a determination as to whether a biomaterials supplier was required to register under the provisions of 21 U.S.C. § 360, *et. seq.* and to request the Commissioner of Food and Drugs to issue a declaration as to whether Lima Corporate, S.P.A., was required to register with the Secretary of Health and Human Services under 21 U.S.C. § 360 *et. seq.* and/or required to include the implant at issue on a list of devices filed with the Secretary pursuant to 21 U.S.C. § 360(j).

A. ACTION REQUESTED.

This Petition specifically requests that the Commissioner make a determination under 21 U.S.C. § 1604(b)(3) regarding whether Lima Corporate S.P.A. was required to register with the Secretary under 21 U.S.C. § 360 and/or list the hip implant device at issue with the Secretary under 21 U.S.C. § 360(j).

B. STATEMENT OF GROUNDS.

The grounds for this petition are that Lima Corporate, S.P.A. is the foreign manufacturer of an artificial hip system known as the Lima Modular Hip System. Pursuant to a Supply Agreement, Lima agreed to sell the Lima Modular Hip System to Encore Medical, L.P. to be distributed in the United States through Encore Medical, L.P.'s subsidiary, DJO Global, Inc. A joint announcement by Lima Corporate and Encore Medical provided that Lima Corporate was providing products for sale in the US through DJO Surgical.

Following execution of the Agreement, DJO submitted a 510(k) application for the Lima Modular Hip System. The 510(k) number for this device was K092331. The 510(k) application included specific technical plans generated by Lima Corporate, S.P.A. for a femoral stem, femoral body, and a locking screw. The application was approved on March 3, 2010.

In April of 2011, the Lima Modular Hip System was implanted in Jeffrey Connell, the petitioner herein. The system was sold by DJO through its representative Rose & Associates. DJO marketed the hip implant as the Lima Modular Hip System and provided information from Lima Corporate as part of the marketing and educational materials.

In October of 2014, the Lima manufactured femoral stem implanted in Mr. Connell fractured, causing significant injury to Mr. Connell. Mr. Connell ultimately filed suit against Lima Corporate

and Encore/DJO. After two years of litigation, Lima Corporate moved for summary judgment asserting that the claims against it were preempted by the Biomaterials Access Assurance Act. Lima Corporate asserted that it was only a biomaterials supplier and not required to register with the Secretary under 21 U.S.C. § 360. As expressly allowed by the statute, 21 U.S.C. § 1604(b)(3), Petitioners now seek a declaration from the Secretary as to the accuracy of this assertion.

Specifically, Petitioners believe that Lima Corporate was required to register under 21 U.S.C. § 360(i)(1) because Lima Corporate operates an establishment in a foreign country engaged in the manufacture, preparation, propagation, compounding or processing of a device, namely the Lima Modular Hip System, imported or offered for import into the United States.

- The Lima Modular Hip System is a device pursuant to 21 U.S.C. § 321(h).
- Lima Corporate operates an establishment in Italy which manufactures the Lima Modular Hip System
- The Lima Modular Hip System was imported into the United States.

Lima Corporate's position will likely be that it merely manufactures raw materials or components to be used in the manufacture or assembly of a device and is not otherwise required to register and is therefore exempt under 21 C.F.R. 807.65(a). Petitioner contends that a device that was submitted for approval as an implant through the 510(k) process is a complete device, not just a component of a device.

Additionally, 21 C.F.R. 807.65 specifically provides that the exemptions apply only to those required to register under 21 C.F.R. 897.20. As a Foreign exporter, Lima Corporate was "otherwise" required to register under 21 C.F.R. 807.40. Petitioners seek a declaration from the Secretary to resolve this question.

Documents attached:

A. 2009 Supply Agreement between Lima Corporate and Encore Medical, L.P.

B. Relevant portions of the 510(k) application for K092331

C. Declaration of Michele Pressacco

D. Joint press releases by Encore/DJO and Lima Corporate

E. Declaration of Caleb Creagan

C. ENVIRONMENTAL IMPACT.

This petition is categorically excluded from requiring an environmental assessment under 21 C.F.R. 25.30.

D. ECONOMIC IMPACT.

Economic impact will be submitted upon request of the commissioner.

E. CERTIFICATION.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

/s/ Eric S. Rossman

Eric S. Rossman
ROSSMAN LAW GROUP, PLLC
350 N. 9th St., Suite 500
Boise, ID 83702
erossman@rossmanlaw.com
208-331-2030 (phone)