April 6, 2018

Biomet Inc.
Dhaval Saraiya
Regulatory Affairs Sr. Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K173767
Trade/Device Name: A. L. P. S. Clavicle Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 22, 2018
Received: March 23, 2018

Dear Dhaval Saraiya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173767

Device Name
A.L.P.S. Clavicle Plating System

Indications for Use *(Describe)*
The A.L.P.S. Clavicle Plating System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle including osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the A.L.P.S. Clavicle Plating System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:

Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact Person:

Dhaval Saraiya
Regulatory Affairs Sr. Specialist
Telephone: (305-269-6386)
Fax: (305-269-6400)

Date:

March 22nd, 2018

Subject Device:

Trade Name: A.L.P.S. Clavicle Plating System
Common Name: Plate, Fixation, Bone

Classification Name:

- HRS – Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Predicate Device(s):

K083843	Locking Anatomic & Composite Plating System	Depuy Orthopaedics*

* The predicate device is included in Biomet's current product portfolio. Biomet acquired DePuy Trauma and as a result of the acquisition of DePuy Trauma, Biomet is now the owner of the predicate device 510(k).

Purpose and Device Description:

The purpose of this submission is to request clearance for the new A.L.P.S Clavicle Plating System. The A.L.P.S Clavicle Plating System implants are designed to address fractures of the clavicle. The system is comprised of plates and instruments to facilitate the installation of the implants. The plates are manufactured from Titanium Alloy per ASTM F136.. Implants and instruments will be

provided in non-sterile configuration and will require steam sterilization prior to use.

Intended Use and Indications for Use:

The A.L.P.S. Clavicle Plating System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle including osteopenic bone.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is similar to the intended use cleared in K083843.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in K083843.
- **Materials:** The new A.L.P. S. Clavicle Plating System plates are manufactured from Titanium Alloy (per ASTM F136). Implant grade titanium alloys are commonly used materials in orthopedic implants.
- **Design Features:** The design features for new A.L.P. S. Clavicle Plating System is similar to those in currently marketed devices cleared in K083843. The design differences have not identified any issues that would impact the safety and effectiveness of the device.
- **Sterilization:** The implants and instruments are offered to the user in the non-sterile configuration. The non-sterile implants and instruments will be required to be steam sterilized by the user prior to use. The non-sterile packaging configuration is similar to the predicate devices currently marketed and cleared via K083843.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Construct Static Testing
  - Galvanic Corrosion Evaluation

- **Clinical Tests:**
  - N/A

Substantial Equivalence

Conclusion	The A.L.P.S. Clavicle Plating System has shown to be substantially equivalent to the predicate device. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.