December 26, 2017

Encore Medical, L.P.
Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Blvd
Austin, Texas 78758

Re: K173073
Trade/Device Name: AltiVate Anatomic to Reverse Conversion Module
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, PAO
Dated: November 9, 2017
Received: November 13, 2017

Dear Teffany Hutto:

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)*
K173073

Device Name
AltiVate Anatomic™ to Reverse Conversion Module

Indications for Use *(Describe)*
The AltiVate Anatomic™to Reverse Conversion Module is indicated for revision surgeries in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The conversion module is only indicated for use with a well fixed AltiVate Anatomic Humeral Stem.

Humeral components with a porous coated surface are indicated for either cemented or uncemented applications. The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: December 15, 2017

Manufacturer:
DJO Surgical (legally Encore Medical, L.P.)
9800 Metric Blvd
Austin, TX 78758

Contact Person:
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Manager, Regulatory Affairs
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Product	Classification	Product Code
AltiVate Anatomic to Reverse Conversion Module	Class II	PHX, KWS, PAO

Product Code	Regulation and Classification Name
PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
KWS	Shoulder joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3660
PAO	Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660

Description:
In cases of revision surgeries to a well fixed AltiVate Humeral Stem, a reverse conversion module can be mated with the AltiVate stem to convert to a reverse shoulder application.

The currently cleared AltiVate™ Anatomic humeral stem will mate with a conversion module to provide an option to revise a failed traditional total shoulder arthroplasty to a reverse shoulder arthroplasty without the need to remove a well fixed humeral stem.

Compatible Components

Component	510(k) Clearance
RSP Socket Inserts	K041066, K051075, K141006
RSP Glenoid Heads	K041066, K051075
RSP Glenoid Baseplate	K041066, K051075

Indications for Use:
The AltiVate Anatomic™ to Reverse Conversion Module is indicated for revision surgeries in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The conversion module is only indicated for use with a well fixed AltiVate Anatomic Humeral Stem.

Humeral components with a porous coated surface are indicated for either cemented or uncemented applications. The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

Predicate Devices:
- DJO Surgical AltiVate™ Anatomic Shoulder System – K162024
- DJO Surgical Reverse® Shoulder Prosthesis - K041066
- DJO Surgical Turon to RSP Conversion Shell - K111629
- DJO Surgical RSP Size 44 Heads – K092873

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same design features, geometry, and dimensions, surface finish, taper angle, indications, intended use, materials, packaging, sterilization, and shelf life.

Key Differences in Subject Device to Predicate Device(s): Insert length, shell length, gage point, taper and shell fillets

Non-Clinical Testing: FEA analysis for stress analysis has determined that the subject device is similar to the evaluated predicate device.

Endotoxin Assessment: Bacterial endotoxin testing was conducted and was found to meet the expected endotoxin limits.

Clinical Testing: Clinical testing was not required / performed.

Conclusions: All testing and evaluations demonstrate that the device is substantially equivalent to the predicates identified.