DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 31, 2015

Skeletal Dynamics, LLC
% John Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street, N.W.
Washington, District of Columbia 20004

Re: K153208
Trade/Device Name: Internal Joint Stabilizer - Elbow
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: OZI, LXT
Dated: November 4, 2015
Received: November 5, 2015

Dear Dr. Smith:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K153208

Device Name

Internal Joint Stabilizer - Elbow

Indications for Use *(Describe)*

The Internal Joint Stabilizer – Elbow is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter:

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Contact person: Ana M. Escagedo

Date Prepared: December 30, 2015

Establishment Registration Number: 3006742481

Name and Classification:

Name:	Internal Joint Stabilizer – Elbow
Common Name:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite
Classification:	21 C.F.R. § 888.3030
Product Code:	OZI; LXT
Class:	II

Predicate Device:

Howmedica (now Stryker) Dynamic Joint Distractor II (K002923)

Device Description – Technological Characteristics:

The Skeletal Dynamics Internal Joint Stabilizer – Elbow is an internal elbow fixator, with three principal components:

- A Base Plate assembly consisting of a low profile Base Plate, contoured to fit within the flat surface of ulna at the olecranon process; a Connecting Rod, a Boom and two Locking Joints designed to bridge over the anconeous muscle. The Connecting Rod and Boom are adjustable by means of the Locking Joints to accommodate different patient anatomies. The Base Plate assembly is made of titanium alloy and cobalt chrome.
- A cobalt chrome Axis Pin threads through the Boom of the Base Plate assembly and is inserted in the axis of rotation of the humerus, and
- Titanium compression screws to attach the Base Plate Assembly to the ulna.

Specialized instrumentation includes Axis Trajectory Guides (available in 3 sizes), K- Wire Guide, K-Wires, Depth Gauges, Drills, a Counter-torque tool, and a T-10 driver and quick connect handle.

The Internal Joint Stabilizer – Elbow is intended to be removed once the elbow ligaments have healed, usually within 6 – 8 weeks after implantation.

The system is provided non-sterile and is sterilized in the user facility.

Intended Use / Indications for Use

The Internal Joint Stabilizer – Elbow is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

Summary of Substantial Equivalence:

The substantial equivalence of the Internal Joint Stabilizer – Elbow to the predicate device is demonstrated by the same intended use, and similar indications for use, materials, design (fundamental scientific technology), performance, sterility, and packaging and does not present any new or different issues of safety and effectiveness.

Performance Data:

Preclinical and clinical analysis and testing demonstrated that the Internal Joint Stabilizer – Elbow is substantially equivalent to the predicate device. Mechanical testing, which established equivalency, included the testing described below:

- Fatigue – Evaluate loosening with repetitive physiological loading.
- Stability – Evaluate IJS-E joint in comparison to Dynamic Joint Distractor II.
- Component Strength – Evaluate grip, torsional and bending strength of the joint components in loading.
- Cadaveric Testing – Demonstrate that the IJS can be consistently implanted and removed in accordance with the surgical technique, and evaluate whether there is soft tissue impingement when used.

Clinical Study:

Clinical testing was also performed in a prospective, multi-center, non-randomized, cohort study, conducted at 6 sites in the US in which 26 subjects were enrolled (26 consented and screened). The purpose of the Internal Joint Stabilizer – Elbow study was to demonstrate safety and effectiveness of the Internal Joint Stabilizer – Elbow. The primary efficacy objective was to confirm that the IJS-E provides temporary stabilization of the elbow joint and allows functional recovery after trauma or chronic dislocation as effectively as hinged external fixation. The primary safety objective was to confirm that the IJS-E does not contribute to a greater number of device related adverse events than hinged external fixation.

Subject outcomes were compared to a retrospective cohort of subjects who underwent external hinged fixation with FDA cleared external fixators at a major metropolitan hospital in the US. A subject was an efficacy success if at six months post explant: the Broberg Morrey Functional Rating was fair or better; and no recurrent dislocation occurred during use of the Internal Joint Stabilizer – Elbow or after its removal. Safety success examined device related adverse events.

Twenty-four (24) out of 26 subjects completed the study; two subjects were lost to follow up. Out of the subjects who completed the study, 23 of the 24 (95.83%) had a Broberg Morrey Functional Rating of Fair or better (95% CI: 78.87%, 99.89%). Out of the 24 subjects who

completed the study, 23 subjects did not have recurrent dislocations (95% CI: 78.87%, 99.89%).

The primary safety objective was also met since the Internal Joint Stabilizer – Elbow did not contribute to a greater number of device related adverse events than the hinged external fixator studied in the retrospective data review. The only device related Adverse Event experienced by the test subject was back out of an Axis Pin (n=1). Other Adverse Events related to the study experienced by study participants included malreduction (N=1).

The Internal Joint Stabilizer – Elbow study demonstrates that the IJS-E will perform equivalently to currently marketed external joint fixation devices in providing temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

Conclusion:
Based on the testing described above evaluating the differences between the subject and predicate device, Skeletal Dynamics concludes that Internal Joint Stabilizer – Elbow is substantially equivalent to the predicate device identified in this premarket notification.