May 10, 2023

Skeletal Dynamics, Inc.
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 N Kendall Drive, Suite 400
Miami, Florida 33156

Re: K223318
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, HRS
Dated: April 20, 2023
Received: April 20, 2023

Dear Alexandra Rodriguez Rojas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.05.10 14:43:44 -04'00'

For: Farzana Sharmin, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223318

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)*

☒ 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
Skeletal Dynamic's
Internal Joint Stabilizer - Elbow

Submitter
Skeletal Dynamics, Inc.
7300 N. Kendall Drive
Suite 400
Miami, FL 33156
Phone: 305-596-7585
Facsimile: 305-596-7591
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: October 21, 2022

Name and Classification
Trade Name: Internal Joint Stabilizer - Elbow
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Common Name: Internal Hinged Elbow Fixator
Classification Number: 21 CFR §888.3030
Regulatory Class: Class II
Product Code: OZI, LXT, HRS

Predicate Devices
Internal Joint Stabilizer – Elbow (K153208)

Reference Devices
Distal Elbow Plating System (K171590)

Device Description
The Skeletal Dynamic's Internal Joint Stabilizer Elbow System (K153208) consists of a titanium base plate, with a Distal Connecting Rod and Proximal Connecting Rod, held together by adjustable locking joints and locking screws which allow for multiple degrees of freedom. The system is being modified to include an Internal Joint Stabilizer - Elbow titanium base plate applied to the Company's cleared Proximal Ulna Plates of the Distal Elbow Plating System (K171590), instead of directly to the ulna as does the base plate of the cleared Internal Joint Stabilizer Elbow System.

The subject Internal Joint Stabilizer- Elbow is attached to the cleared Proximal Ulna Plates by means of two #4-40 cobalt chrome screws of 5.5mm in length and the Proximal Connecting Rod is secured to the distal humerus at the axis of rotation using the cleared cobalt chrome axis pin provided in multiple lengths from 30mm to 70mm in 5mm increments. The modified system provides internal stabilization to the elbow joint in the same manner, function, and technology as the Company's cleared Internal Joint Stabilizer Elbow. The system includes specialized instrumentation.

When attached to the cleared Skeletal Dynamics proximal ulna plate, the Internal Joint Stabilizer Elbow sits on the same anatomical location over the ulna and under the musculature and soft tissue, as does the cleared Internal Joint Stabilizer – Elbow.

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

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 Technological Characteristics

The substantial equivalence of the Internal Joint Stabilizer Elbow to the predicate devices is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging and does not present any different questions of safety or effectiveness. The device has the same intended use and indications for use as the Company's Internal Joint Stabilizer – Elbow (K153208).

Performance Testing

Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamic's Internal Joint Stabilizer Elbow is equivalent to its predicate device currently marketed. Mechanical testing which established equivalency included static and fatigue testing of the construct applied to Skeletal Dynamic's cleared Proximal Ulna Plate. Based on the verification results, the subject device is as safe and effective as the legally marketed predicate device.

Conclusions

The Skeletal Dynamic's Internal Joint Stabilizer - Elbow is substantially equivalent to the Internal Joint Stabilizer Elbow predicate device identified in this premarket notification.