Skeletal Dynamics Inc
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 North Kendall Drive
Miami, Florida 33156

December 15, 2023

Re: K231447
Trade/Device Name: Double 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 10, 2023
Received: November 13, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2023.12.15 11:47:03 -05'00'

for: Farzana Sharmin, PhD
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)*

K231447

Device Name

Double Internal Joint Stabilizer- Elbow

Indications for Use *(Describe)*

The Double 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.

510(k) SUMMARY
Skeletal Dynamic's
Double 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: May 17, 2023

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

Primary Predicate Device
Internal Joint Stabilizer – Elbow (K153208)

Reference Device
Internal Joint Stabilizer - Elbow (K223318)

Device Description
The Predicate Internal Joint Stabilizer - Elbow (IJS-E) System consists of a titanium base plate, with the following components: 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 Proximal Connecting Rod is secured to the distal humerus at the axis of rotation using a cobalt chrome axis pin provided in multiple lengths from 30mm to 70mm in 5mm increments.

The subject Double Internal Joint Stabilizer - Elbow (IJS-E) System is modifying the predicate IJS-E Base Plate to add an additional set of components to the other side of the IJS-E Base plate. The Proximal Connecting Rods from each side of the Double IJS-E base plate are secured to the distal humerus at the axis of rotation using the predicate male axis pin from one side and the new female axis pin from the other side. The male axis pin telescopes within the female axis pin within the distal humerus.

The subject Double Internal Joint Stabilizer - Elbow Base Plate is attached to the Ulna by the same 3.5mm compression screws as the predicate IJS-E system (K153208). 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.

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

Indications for Use

The Double 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. While there are differences in the design, these differences do not present any different issues of safety or effectiveness.

Performance Testing
Fatigue and stability testing demonstrated that the subject Double Internal Joint Stabilizer - Elbow is equivalent to its predicate device currently marketed. 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.