Skeletal Dynamics, LLC
Ana Escagedo
President
8905 SW 87 Avenue, Suite 201
Miami, Florida 33176

April 11, 2018

Re: K180744
Trade/Device Name: Stablyx CMC Arthroplasty Implant System
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist Joint Carpal Trapezium Polymer Prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: March 20, 2018
Received: March 22, 2018

Dear Ana Escagedo:

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)*
K180744

Device Name
Stablyx CMC Arthroplasty Implant System

Indications for Use *(Describe)*
The Stablyx CMC Arthroplasty Implant System is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either painful, unstable thumb or a thumb with limited range of motion. The implant is intended for uncemented, press fit use.

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 of Safety and Effectiveness
Skeletal Dynamics Stablyx CMC Arthroplasty Implant System

March 20, 2018

Submitter:
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Contact: Ana M. Escagedo, Vice President
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Establishment Registration Number: 3006742481

Name and Classification:

Name	Stablyx CMC Arthroplasty Implant System
Common Name	Prosthesis, wrist, carpal trapezium
Classification	21 CFR §888.3770
Product Code	KYI
Class	Class II

Predicate Devices:
Stablyx CMC Arthroplasty Implant System (K111068)

Description of the Device:
The Stablyx CMC Arthroplasty System is a hemi monoblock prosthesis for replacement of the first metacarpal carpometacarpal (CMC) joint. The single piece prosthesis has a highly polished, saddle shaped (toroidal) articular surface which mirrors the normal anatomy of the base of the first metacarpal. The saddle surface of the Stablyx CMC prosthesis articulates against the saddle surface of the trapezium, allowing for flexion-extension, abduction-adduction and opposition motions.

The prosthesis is available in fixe sizes, and is made of Cobalt Chrome (CoCr) with a Titanium Plasma Spray (TPS) coated stem which may assist in biological fixation. The stem is intended to press fit into the medullary canal. Each prosthesis is packaged and provided sterile.

The Stablyx CMC Arthroplasty System is comprised of:

- Multiple sized hemi joint prosthesis
- System specific instrumentation

Intended Use:
The Stablyx CMC Arthroplasty Implant System is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture

deformation or bone loss which present as either a painful, unstable thumb or a thumb with limited range of motion. The implant is intended for uncemented, press fit use.

Technological Characteristics:
The substantial equivalence of the Stablyx CMC Arthroplasty Implant System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:
Engineering analysis and testing demonstrated that the Stablyx CMC Arthroplasty System is substantially equivalent to the predicate device currently marketed. Characterization testing, including gravimetric testing and analysis established equivalency. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:
The Skeletal Dynamics Stablyx CMC Arthroplasty System is substantially equivalent to the predicate device identified in this premarket notification.