March 11, 2021

Stryker Endoscopy
Victoria Milich
Staff Regulatory Compliance Specialist
5900 Optical Court
San Jose, California 95138

Re: K210078
Trade/Device Name: Stryker ProCinch Adjustable Loop Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 8, 2021
Received: January 12, 2021

Dear Victoria Milich:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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.

510(k) Number *(if known)*

K210078

Device Name

ProCinch Adjustable Loop Device (Configurations: Reverse Tensioning, Standard Tensioning, and No Button).

Indications for Use *(Describe)*

The Stryker ProCinch Adjustable Loop Fixation Device is intended for the fixation of bone-to-bone or soft tissue-to-bone as fixation posts, a distribution bridge, or for distributing suture tension during ligament or tendon repair and reconstruction procedures such as Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Patellofemoral Ligament (MPFL), and Posterolateral Corner (PLC).

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.

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Section 006: 510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138

Contact Person: Victoria Milich, RAC
Staff Regulatory Compliance Specialist
Phone: 508-642-6132

Date Prepared: 08-January-2021

II. DEVICES

Trade Name: Stryker ProCinch Adjustable Loop Device
Configurations: Standard Tensioning, Reverse Tensioning, No Button
Common Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI

III. PREDICATE DEVICE

Predicate Device: Stryker ProCinch Adjustable Loop Device
Configurations: Standard Tensioning, Reverse Tensioning
Company Name: Stryker
510(k) Number: K150416
This predicate has not been subject to a design-related recall.

IV. Objective

The ProCinch Adjustable Loop Device product family currently consists of two cleared configurations, Standard Tensioning (ProCinch ST) and Reverse Tensioning (ProCinch RT). The purpose of this Traditional 510(k) submission is to obtain Food and Drug Administration (FDA) authorization to market a modified ProCinch Adjustable Loop Device. Specifically, this submission proposes two unrelated modifications to Stryker's legally marketed ProCinch Adjustable Loop Device: 1) a line extension that introduces a new configuration, the ProCinch No Button Adjustable Loop Implant, and 2) an expansion in the indications for use to include two additional ligament and tendon repair and reconstruction procedures - Medial Patellofemoral Ligament (MPFL), and Posterolateral Corner (PLC).

V. DEVICE DESCRIPTION

Stryker Endoscopy is introducing a new device configuration as a line extension to the ProCinch product family, the Stryker ProCinch No Button Adjustable Loop Implant (ProCinch NB), for use in orthopedic applications.

All ProCinch Adjustable Loop device configurations are cortical suspension fixation implants that consist of an adjustable, implantable nonabsorbable UHMWPE/polyester suture loop. The ProCinch RT and ProCinch ST configurations have three non-implanted polyester sutures that are intended to facilitate insertion of the implant and flipping of the button. The ProCinch RT and ProCinch ST configurations are provided preassembled to a titanium button. The ProCinch NB configuration contains one non-implanted polyester suture that is intended to facilitate insertion of the implant. The ProCinch NB configuration is provided without a titanium button; it is intended to be used with a separate compatible button to achieve fixation. The user will assemble a compatible button to the ProCinch NB suture loop after passing the suture loop implant through the bone tunnel. All configurations are provided sterile and are labeled for single use.

VI. INDICATIONS FOR USE

The Stryker ProCinch Adjustable Loop Fixation Device is intended for the fixation of bone-to-bone or soft tissue-to-bone as fixation posts, a distribution bridge, or for distributing suture tension during ligament or tendon repair and reconstruction procedures such as Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Patellofemoral Ligament (MPFL), and Posterolateral Corner (PLC).

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed and predicate devices are cortical suspension fixation devices that allow for intraoperative adjustability of cortical fixation through the same operational principle. The proposed device is identical to the predicate in terms of intended use, raw material intended for implantation, operational principle, sterility, packaging and performance requirements. It is substantially equivalent in terms of general design features.

The ProCinch NB configuration is comprised of an implantable suture loop and one non-implanted suture. The user must assemble a compatible slotted button to the ProCinch NB configuration following insertion of the implant through the bone tunnel to achieve fixation. The predicate device configurations, ProCinch RT and ProCinch ST, contain the same components, plus two additional non-implanted sutures and a pre-assembled titanium button for fixation.

The minor differences between the proposed and predicate device do not raise new questions of safety and effectiveness, and these devices are substantially equivalent based on the criteria described in 21 CFR 807.100.

VIII. PERFORMANCE DATA/NON-CLINICAL TESTING

Non-clinical benchtop testing was performed to evaluate the performance characteristics of the ProCinch NB configuration, including cyclic extension and ultimate tensile strength (UTS). The ProCinch NB configuration met all acceptance criteria established by the predicate device, and no new issues of safety and effectiveness were identified.
Testing for material-mediated pyrogenicity and bacterial endotoxins was performed, with passing results below the required limits.

IX. CONCLUSIONS

The information presented within this traditional premarket submission demonstrates that the proposed device is substantially equivalent to the predicate configurations and will perform as safety and as effectively within the intended use.