October 16, 2020

Howmedica Osteonics Corp., dba Stryker Orthopaedics
Margaret Klippel
Senior Principal RA Project Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K202016
Trade/Device Name: Dall-Miles® Cable System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS, LYT, LRN
Dated: July 20, 2020
Received: July 21, 2020

Dear Margaret Klippel:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202016

Device Name
Dall-Miles® Cable System

Indications for Use *(Describe)*
The DALL-MILES System is indicated for reattachment of the trochanter in any hip procedure using the trochanteric osteotomy (total or partial) approach.

The DALL-MILES Mini Cleat is indicated for vertical reattachment or reinforcement of the trochanter in any situation where the surgeon feels that the trochanter is at risk for detachment.

The Mini Cleat is intended for use with the DALL-MILES System for trochanteric reattachment only.

The DALL-MILES Cables and Cable Sleeves are indicated for trochanteric reattachment and trauma surgery of the hip; to stabilize bone graft material; and for supplementary cerclage fixation with plates and screws for fracture fixation.

The DALL-MILES Trochanteric Grips and Grip Plates are indicated for use in the fixation of the greater trochanter due to trochanteric fracture or osteotomy with intramedullary fixation as the primary device.

The DALL-MILES Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

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

Sponsor Stryker Orthopaedics
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Mahwah, NJ 07430

Contact Person Margaret Klippel
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Telephone: 201-831-5559
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Date Prepared: October 14, 2020

Proprietary Name: Dall-Miles® Cable System

Common Name: Bone fixation accessories

Regulatory Class: Class II

Regulation: Single/multiple component metallic bone fixation appliances and accessories (888.3030)
Bone fixation cerclage (888.3010)

Product Codes: HRS, JDQ, LYT, LRN

Predicate Devices

Primary Predicate Device: K070170

Additional Secondary Predicate Devices: K971741, K961283, K953818, K945294, K934058, and K900926

Product Name	Previous Premarket Notifications
Dall-Miles Stainless Steel Cable Dall-Miles Cable and Sleeve Set	K971741
Dall-Miles Cable Sleeve	K900926
Dall-Miles Trochanteric Grip (Stainless Steel) Dall-Miles Trochanteric Grip Plate (Stainless Steel) Dall-Miles Trochanteric Grip with 2 cables (CoCr) Dall-Miles Trochanteric Grip Plate with 2 cables (CoCr)	K070170

Product Name	Previous Premarket Notifications
Dall-Miles CoCr Cable	K945294 K961283
Dall-Miles Cable Sleeve Dall-Miles Cable Grip	K900926
Dall-Miles Cable and Sleeve Set	K945294 K953818
Dall-Miles Cable Set Cable Grip	K945294
Dall-Miles Mini-Cleat	K934058

Device Description:
The devices covered by this submission include cables, beaded cables, cable sleeves, trochanteric grips, trochanteric grip plates, and mini cleat. All devices have been previously determined substantially equivalent in prior 510(k) submissions and are commercially available. The Dall-Miles Cable System components are manufactured from stainless steel or cobalt chromium alloy (Vitallium®) materials.

The purpose of this submission is to modify the labeling of the Dall-Miles Cable System to add MR Conditional labeling.

Indication for Use:
The indications for the subject components are as follows:

The DALL-MILES System is indicated for reattachment of the trochanter in any hip procedure using the trochanteric osteotomy (total or partial) approach.

The DALL-MILES Mini Cleat is indicated for vertical reattachment or reinforcement of the trochanter in any situation where the surgeon feels that the trochanter is at risk for detachment.

The Mini Cleat is intended for use with the DALL-MILES System for trochanteric reattachment only.

The DALL-MILES Cables and Cable Sleeves are indicated for trochanteric reattachment and trauma surgery of the hip; to stabilize bone graft material; and for supplementary cerclage fixation with plates and screws for fracture fixation.

The DALL-MILES Trochanteric Grips and Grip Plates are indicated for use in the fixation of the greater trochanter due to trochanteric fracture or osteotomy with intramedullary fixation as the primary device.

The DALL-MILES Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

Summary of Technological Characteristics: There have been no changes to the technological characteristics of the subject cable system devices as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:
The following non-clinical laboratory testing was performed to determine substantial equivalence:

Non-clinical testing as outlined in the FDA guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff", dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics Dall-Miles Cable System in the MR environment. FDA guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Guidance for Industry and FDA Staff", dated March 22, 2016 was also consulted for the heating evaluations performed. Testing was performed according to the standards listed below:

- Magnetically Inducted Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment

- Magnetically Induced Torque – performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment

- Image Artifact – performed per ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from passive Implants

- Heating by RF Fields per ASTM F2182-19, Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during MR Imaging

The labeling has been modified to include the MR conditional symbol, and to provide the parameters under which a patient who has the device can be safely scanned.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Dall-Miles Cable System components are substantially equivalent to the predicate devices identified in this premarket notification.