June 4, 2024

Relign Corporation, Subsidiary of Zimmer Biomet
Tadakala Saikanth
Senior Regulatory Affairs Specialist
655 Campbell Technology Parkway
Suite 275
Campbell, California 95008

Re: K241008
Trade/Device Name: Tricera Arthroscopic System; Tricera Controller (R-10001); Tricera Handpiece, Autoclavable (R-10023); Veriflow (R-10003); Exoflow (R-10017); 3-in-1 Shaver 4.2mm (R-10008); 3-in-1 Shaver 5.0mm (R-10014); Dynablator (R-10005); Standard Burr 5.0mm (R-10021); Standard Shaver 3.4mm (R-10012); Curved Standard Shaver 3.4mm (R-10024); Curved Standard Ball Burr XL, 5.0mm (R-10025); Curved Shaver XL 4.2mm (R-10026); Curved Dynablator, XL (R-10027)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: HRX, GEI

Dear Tadakala Saikanth:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 8, 2024. Specifically, FDA is updating this SE Letter with appropriate regulation number and regulation name, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jesse Muir, Ph.D., OHT6: Office of Orthopedic Devices, 240-402-6679, Jesse.Muir@fda.hhs.gov.

Sincerely,

Jesse Muir -S
Digitally signed by Jesse Muir -S
Date: 2024.06.04 10:01:36 -04'00'

Jesse Muir, 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

May 8, 2024

Relign Corporation, Subsidiary of Zimmer Biomet
Tadakala Saikanth
Senior Regulatory Affairs Specialist
655 Campbell Technology Parkway
Suite 275
Campbell, California 95008

Re: K241008
Trade/Device Name: Tricera™ Arthroscopic System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GEI
Dated: April 11, 2024
Received: April 12, 2024

Dear Saikanth Tadakala:

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.05.08 11:28:53 -04'00'

Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241008

Device Name

Tricera™ Arthroscopic System

Indications for Use *(Describe)*

The Tricera™ Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Tricera™ Arthroscopic System provides fluid distension and irrigation of the knee, shoulder, ankle, elbow, wrist and hip, and fluid suction during diagnostic and operative arthroscopic procedures. The Shaver Blade/RF Probe of the Tricera™ Arthroscopic System provides abrasion, resection, debridement, and removal of bone through its shaver blade; removal, ablation, and coagulation of soft tissue; as well as hemostasis of blood vessels through its shaver blade and probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.
Contraindications: The electrosurgical probe should not be used in procedures where a nonconductive irrigant is used or with patients having cardiac pacemakers or other electronic implants.

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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ZIMMER BIOMET
655 Campbell Technology Parkway, Suite 275, Campbell, CA 95008, USA

Special 510(k) Summary

1. Date Prepared: May 07, 2024

2. Sponsor Name and Address:

Relign Corporation, a subsidiary of Zimmer Biomet

655 Campbell Technology Parkway, Suite 275

Campbell, CA 95008 USA

Phone: 330-260-4298

Contact: Saikanth Tadakala, Senior Regulatory Affairs Specialist, Regulatory Affairs

3. Device Name:

Trade Name: Tricera™ Arthroscopic System

Common Name: Arthroscope and Electrosurgical Cutting & Coagulation Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Product Code: GEI, HRX

4. Predicate Device:

Trade Name: Tricera™ Arthroscopic System

Common Name: Arthroscope and Electrosurgical Cutting & Coagulation Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Product Code: GEI, HRX

510(K) Numbers: Primary Predicate-K233493
Additional Predicate-K162770

5. Device Description:

The device description and principles of operation for the modified devices are equivalent to the device description of the predicate devices cleared per Primary Predicate-K233493 and

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additional predicate-K162770. A brief device description of the subject devices is provided in the table below.

Device	Description
Curved Standard Ball Burr XL, 5.0mm	An arthroscopic burr that provides abrasion, resection, debridement, and removal of bone. The Curved Dynablator XL is specifically designed for use in hip joints with a spherical ball burr and bent outer tube for access to hip pathology.
Curved Standard Shaver XL, 4.2mm	An arthroscopic shaver that provides resection and removal of soft tissue. The Curved Dynablator XL is specifically designed for use in hip joints with a bent outer tube for access to hip pathology.
Curved Dynablator XL	An arthroscopic RF probe that provides removal, ablation, and coagulation of soft tissue; as well as hemostasis of blood vessels. The Curved Dynablator XL is specifically designed for use in hip joints with a bent outer tube for access to hip pathology.

6. Indications for Use:

The Tricera™ Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Tricera™ Arthroscopic System provides fluid distension and irrigation of the knee, shoulder, ankle, elbow, wrist and hip, and fluid suction during diagnostic and operative arthroscopic procedures. The Shaver Blade/RF Probe of the Tricera™ Arthroscopic System provides abrasion, resection, debridement, and removal of bone through its shaver blade; removal, ablation, and coagulation of soft tissue; as well as hemostasis of blood vessels through its shaver blade and probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.

Contraindications: The electrosurgical probe should not be used in procedures where a nonconductive irrigant is used or with patients having cardiac pacemakers or other electronic implants.

7. Technological Characteristics:

The proposed modification does not change the fundamental design, operating principles and the intended/indications for use of the Tricera™ Arthroscopic System Therefore, the technological characteristics of the modified device remain substantially equivalent to that of the primary predicate device (K233493) and additional predicate(K162770). The modified Tricera™ Arthroscopic System is substantially equivalent to the legally marketed predicate device Tricera™ Arthroscopic System primary predicate (K233493) and additional Predicate(K162770) in that these devices are identical in use, utilize similar materials, and operate using the same fundamental design principles. Details on specific technological characteristics of the subject and predicate devices are provided in the table below.

Feature	Discussion

Soft Tissue Cutting Edges	Both the subject and predicate devices utilize sharp cutting edges to provide resection of soft tissue within the joint. The tip containing the cutting edges of the subject device were increased to provide more efficient tissue cutting.
Spiral Cut Inner Tube	Both the subject and predicate devices utilize a spiral cut inner tube in order to rotate inside of the bent outer tube while providing an open lumen for tissue removal.
Inner Tube Coupler	Both the subject and predicate devices utilize a coupler which engages with the shaver handpiece in order to transfer rotational energy from the handpiece motor to the distal tip of the device through the inner tube member.
Bone Cutting Flutes	Both the subject and predicate devices utilize bone cutting flutes on a burr which rotate to abrade and resect bone. The burr of the subject device was modified to a spherical shape to provide more effective bone resection in hip joints.
Electrode and Ceramic Geometry	Both the subject and predicate devices utilize a reciprocating electrode within a ceramic insulation to provide efficient bulk tissue resection and removal while in motion, while also maintaining ablation and coagulation abilities when the electrode is stationary. The subject device has a modified electrode and ceramic geometry in order to provide efficient operation while reciprocating through a bend in the outer tube.

8. Performance Data:

Performance data for all modifications are provided in the Packaging (Transit), Verification and Validation, Shelf Life, Software, and EMC attachments to the 510(k). All modifications were tested to standardized or equivalent test methods established in the primary predicate device 510(k) K233493 and additional predicate 510(k) K162770.

9. Conclusions:

The Tricera™ Arthroscopic System with modification is determined to remain substantially equivalent to the FDA-cleared (per K233493) Tricera™ Arthroscopic System (a primary predicate device) and FDA-Cleared K162770(additional predicate) .