



November 28, 2023

Relign Corporation  
Nathan Nguyen  
Director, Quality and Regulatory Affairs  
655 Campbell Technology Parkway  
Suite 275  
Campbell, California 95008

Re: K233493

Trade/Device Name: Tricera Arthroscopic System; Tricera Controller (R-10001); Tricera Shaver Handpiece (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 (R-10021); Standard Shaver 3.4mm (R-10012); Curved Standard Shaver 3.4mm (R-10024)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulatory Class: Class II

Product Code: GEI, HRX

Dated: October 27, 2023

Received: October 30, 2023

Dear Nathan Nguyen:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Sara S. Thompson -S**

For

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

## Indications for Use

K233493

Device Name

Tricera Arthroscopic System;  
Tricera Controller (R-10001);  
Tricera Shaver Handpiece (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 (R-10021);  
Standard Shaver 3.4mm (R-10012);  
Curved Standard Shaver 3.4mm (R-10024)

Indications for Use (Describe)

The Relign Tricera Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Relign 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 Relign 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Special 510(k) Summary

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**1. Date Prepared:** October 27, 2023

**2. Sponsor Name and Address:**

Relign Corporation, a subsidiary of Zimmer Biomet  
655 Campbell Technology Parkway, Suite 275  
Campbell, CA 95008 USA  
Phone: 408-484-7428  
Fax: 408-740-3071

Contact: Nathan Nguyen, Director, Quality Assurance & 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: Relign 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) Number: K162770

**5. Device Description:**

The device description for the modified device is identical to the device description of the predicate device cleared per K162770 with the exception of the sterilization methods for Relign’s Shaver Handpiece, a component device of the Tricera Arthroscopic System, which is being changed as follows:

Current Methods	Proposed Methods	New Available Methods
STERRAD 100S		STERRAD 100S
STERRAD 100NX		STERRAD 100NX
STERRAD NX		STERRAD NX
	Steris V-PRO Lumen Steam Autoclave	Steris V-PRO Lumen Steam Autoclave

## 6. Indications for Use:

The Relign Tricera Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Relign 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 Relign 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 electro-surgical 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 Relign's Tricera Arthroscopic System. Therefore, the technological characteristics of the modified device remain substantially equivalent to that of the predicate device (K162770). The modified Tricera Arthroscopic System is substantially equivalent to the legally marketed predicate device Tricera Arthroscopic System (K162770) in that these devices are identical in use, utilize similar materials, and operate using the same fundamental design principles.

## 8. Performance Data

The newly proposed sterilization methods for Relign's Shaver Handpiece were validated in accordance with the "Overkill Sterilization Method" per AAMI TIR12:2010 and ISO 14937:2009. The performance testing has validated that the cycle parameters of each sterilization cycle evaluated are safe and effective and able to achieve an SAL of  $10^{-6}$  when processing Relign's Shaver Handpiece. In addition, the analysis results of the sterilization residuals indicated that the maximum residual levels and tolerable contact limits were below the levels defined in the protocol acceptance criteria.

Reprocessing functionality testing was also repeated with the newly proposed autoclave steam sterilization method in order to verify that Relign's Shaver Handpiece is able to successfully withstand the exposure of anticipated reprocessing conditions. The results of the verification indicated that the device was able to maintain its performance for the estimated duration of expected use, confirming that there are no new functional risks introduced from the proposed autoclave steam sterilization method when compared to the predicate (K162770) device (R-10002 Shaver Handpiece).

**9. Conclusions**

Relign concludes that the latest modified (subject) Tricera Autoclavable Shaver Handpiece (R-10023) remains substantially equivalent to the 510(k)-cleared (K162770) Tricera Shaver Handpiece (R-10002) and does not have any adverse impact when used with Relign's Tricera Arthroscopic System. Furthermore, Relign's Tricera Arthroscopic System with modification is determined to remain substantially equivalent to the FDA-cleared (per K162770) Relign Arthroscopic System (a predicate device).