DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 4, 2017

ReLIGN Corporation
Mr. Nathan Nguyen
Sr. Director, Quality Assurance & Regulatory Affairs
1601 South De Anza Boulevard, Suite 200
Cupertino, California 95014

Re: K162770
Trade/Device Name: ReLIGN Arthroscopic System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HRX
Dated: December 2, 2016
Received: December 5, 2016

Dear Mr. 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 (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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162770

Device Name

Relign Arthroscopic System

Indications for Use *(Describe)*

The Relign Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Relign 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 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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510(k) Summary

1. Date Prepared: December 22, 2016

2. Submitter Name and Address:

ReLIGN Corporation
1601 South De Anza Boulevard, Suite 200
Cupertino, CA 95014
Phone: (408) 996-2517 Ext. 320
Fax: (408) 642-1455
Contact: Nathan Nguyen, Sr. Director, Quality Assurance & Regulatory Affairs

3. Device Name:

Trade Name:	Relign Arthroscopic System
Common Name(s):	Arthroscope and Electrosurgical Cutting & Coagulation Device and Accessories; Arthroscopic Pump, Tubing Sets and Accessories
Classification Name(s):	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400); and Arthroscope and Accessories (21 CFR 888.1100)
Product Code:	GEI, HRX

4. Predicate Devices:

K071859	Stryker Crossfire Integrated Arthroscopy System
K123441	Stryker CrossFlow Integrated Arthroscopy Pump

5. Device Description:

The Relign Arthroscopic System is a combination radiofrequency controller, shaver system, and fluid management system. The integrated system simultaneously controls a reusable shaver handpiece with disposable shaver blades and probes that include electrosurgical energy, as well as fluid management through inflow and outflow pumps that operate on the peristaltic principle. The system is comprised of five (5) major system components: The Relign Controller that includes a Footswitch, a reusable Shaver Handpiece, a disposable sterile single-use Combination Shaver Blade, a disposable sterile single-use Reciprocating RF Probe, and a disposable sterile single-use Fluid Management Accessories.

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6. Indications for Use:

The Relign Arthroscopic System is indicated for use in orthopedic and arthroscopic procedures. The Fluid Management System of the Relign 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 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 Relign Arthroscopic System is substantially equivalent to the predicate devices. The Relign Controller provides control to the Fluid Management Accessories to deliver fluid under pressure control to the joint, control to the Shaver Handpiece for arthroscopic shaving and bone burring, and RF power through the shaver handpiece into the RF shaver blades/probes. The Shaver Handpiece is an electrically powered, hand-held surgical instrument that uses interchangeable shaver blades/probes to abrade and remove bone and debride soft tissue. The Shaver Handpiece has RF contacts which connect to the shaver blades/probes to deliver RF to the tissue sufficient for the resection, ablation, and coagulation of soft tissue within the joint. The Shaver Handpiece features hand switches for controlling shaver parameters, a screen providing visual indication of shaver parameters, and a suction irrigation port for removing fluid and tissue from the operating site. The shaver blade/probe is an arthroscopic shaver blade that provides abrasion, resection, debridement, and removal of bone; removal, ablation, and coagulation of soft tissue; as well as hemostasis of blood vessels. The Fluid Management Accessories provides control of the infusion and outflow of fluids within the joint space. Fundamentally, the Relign Arthroscopic System simply combines well-known and understood device types into one integrated system to abrade, resect, debride, and remove bone; remove, ablate and coagulate soft tissues; as well as provide hemostasis of blood vessels.

8. Bench Performance Data

The Relign Arthroscopic System performance was tested in accordance with design specifications and with voluntary external standards. Performance testing to design specifications included: flow rate testing, pressure control testing, electrode temperature and coagulation depth testing, mechanical testing, durability testing, simulated use testing, cadaver testing, distribution testing, and shelf life testing. The bench testing performed on the Relign Arthroscopic System verifies that the device satisfies design specifications and acceptance criteria. Software was developed, tested, and verified per FDA guidance

documents and IEC 62304:2006. Electrical safety and electromagnetic compatibility testing were verified per IEC 60601-1:2005, IEC 60601-2-2:2009, and IEC 60601-1-2:2014. The biocompatibility of the patient contacting materials of the Relign Arthroscopic System, specifically the Shaver Handpiece, Combination Shaver Blade, Reciprocating RF probe and Fluid Management Accessories component devices, was assessed in accordance with ISO 10993:2009 and FDA's "Guidance for Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 16 June 2016." Biocompatibility was demonstrated based on the results of biological assessment and testing performed on the materials. The sterile disposable devices were validated for use with Gamma Irradiation in accordance with VDmax method as outlined in ANSI/AAMI/ISO 11137-2:2013. The results were found to be acceptable, thus substantiating that the minimum sterilization dose evaluated provides a SAL of 10^{-6}. The Relign Shaver Handpiece was validated for use with STERRAD sterilization. The low temperature plasma sterilization process was validated in accordance with the "Overkill Sterilization Method" per AAMI TIR12:2010 and ISO 14937:2009. The results were found to be acceptable, thus substantiating that each sterilization cycle evaluated provides a SAL of 10^{-6}. Pursuant to FDA's Guidance, "Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design", Human Factors testing was performed on the Relign Arthroscopic System. Both Formative and Summative Testing were conducted to determine whether users trained per the IFU were able to set-up and operate the Relign Arthroscopic System. User testing demonstrated that the users were able to successfully execute the test scenarios without failures. The minor differences in the design between the Relign Arthroscopic System and the predicate devices do not raise any new types of safety or effectiveness questions as confirmed by design verification testing.

9. Substantial Equivalence

Based on the results of the Bench Performance, Biocompatibility, Cadaver Studies and Usability Testing, the Relign Arthroscopic System with integrated functionality is substantially equivalent to the currently cleared Stryker Crossfire RF and Shaver System (K071859) and Stryker CrossFlow Integrated Arthroscopy Pump (K123441) with respect to intended use/indication for use, technological characteristics, and principles of operation. The minor differences in the design between the Relign Arthroscopic System and the predicate devices do not raise any new types of safety or effectiveness questions as confirmed by design verification testing. Therefore, the Relign Arthroscopic System is substantially equivalent to the previously-cleared predicate devices.

The following comparison tables show the similarities and differences regarding the technological characteristics of the subject and the predicate devices:

Table 9-1: Radiofrequency Comparison		
Feature	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker Crossfire
Bipolar Ablation Radiofrequency	Yes	Same
RF Max Power (W)	400W	Same
RF peak Voltage (V)	500V	400V
RF Frequency(kHz)	225kHz	200kHz
Waveform	Square Wave	Same
Crest Factor	<1.6 @175 ohms	<1.5 @ 200 ohms
Bipolar Coagulation	Yes	Same
RF Coagulation Max Power (W)	50w	Coag 1: 20w, Coag 2: 30w, Coag 3: 50w
RF Coagulation Peak Voltage (V)	180V	150V
RF Coagulation Frequency (kHz)	225kHz	200kHz

Table 9-2: Shaver Control and Shaver Handpiece Comparison				
Feature	**Subject Device** Relign Arthroscopic System		**Predicate Device** Stryker Crossfire	
Maximum RPM	15,000		12,000	
Oscillate maximum RPM	5,000		3,000	
RF Shaver Mode	Simultaneous RF activation and motor activation		Same	
Shaver Handpiece Motor peak torque	1.5in*lbs.		1.4in*lbs.	
Graphical display of settings	Yes	The Relign Controller contains a graphical display which displays the shaver settings: mode of operation, rotational speed, ablation power, and suction levels can be controlled from the touch screen graphical display	Yes	Controller screen displays the RF power levels and the rotational speed. (The suction levels are displayed on the Stryker Crossflow graphical display)
	Yes	The Relign Shaver Handpiece contains an integrated LCD screen which displays rotational speed, ablation power levels, and suction levels		

Table 9-2: Shaver Control and Shaver Handpiece Comparison		
Feature	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker Crossfire
Control of Handpiece settings (rpm, oscillate, etc.)	Control of the Shaver Handpiece settings on the graphical display on the Controller touch screen, using the buttons and graphical display on the Handpiece, or using the foot pedal	Control of Handpiece settings on the graphical display on the Controller touch screen, using the buttons on the Shaver Handpiece, or using foot pedal
Functions activated by the Shaver Handpiece	• Shaver Handpiece motor activation on Handpiece • RF ablation activation on Shaver Handpiece • Coagulation activation on Shaver Handpiece	• Shaver Handpiece motor activation on Handpiece
Suction lever	Electronic Suction lever: Suction is controlled through the software communication with joystick on the Handpiece	Physical Suction lever which controls the opening and closing of a valve in the suction channel
RF	Bipolar radiofrequency contacts within the Handpiece	No RF contacts within the Handpiece
Biocompatibility	Yes. Fluid Contacting	Same
Cleaning Validation of Reusable Handpiece	User manual instructs end-user manually clean Shaver Handpiece prior to sterilization cleaning steps validation & verification per FDA Guidance for Reprocessing Medical Devices in Health Care Settings – Validation Methods and Labeling, March 17, 2015	Same
Sterilization Validation of Reusable Handpiece	Sterrad 100s Sterrad 100NX Sterrad NX	Steam sterilization (Flash, PreVac, Gravity) Sterrad 100s 100% EO ETO/Oxyfume 2002

Table 9-3: Fluid Management Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker CrossFlow
Fluid Management:	Fluid Management Inflow Pump Type	Peristaltic Pump	Same

Table 9-3: Fluid Management Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker CrossFlow
Inflow	Maximum Average Flow Rate (ml/min)	1150	1200
	Pressure Sensing (1)	In-line pressure sensing measuring the pressure within the inflow tubing and subsequently the joint	Same
	Pressure Sensing (2)	Direct in-joint pressure sensing	N/A
	Joint Pressure setting range	15-150mmHg	Same
	Default joint pressure settings	Knee: 45mmHg Shoulder: 50mmHg Hip: 50mmHg Small Joint: 35mmHg	Same
	Cannula Sheath calibration	Yes	Same
	Stored Cannula sheath combinations	No	Yes
	Tube set presence detection	Yes	Same
Fluid Management: Aspiration	Fluid Management Outflow Pump Type	Peristaltic Pump	Same
	Maximum Average Flow Rate (ml/min)	950	850
	Suction	Outflow Peristaltic Pump	Same
	Suction pinch valves	No pinch valves. The Relign Arthroscopic System combines RF and Shaver into a single unit as such switching the suction is not necessary.	Suction pinch vales direct the suction between different suction tubes. Ex. Pinch valve will switch between RF probe suction or shaver suction depending which is activated
	Clear/Wash Mode	Increased flow activated to clear field of view	Increased flow activated to clear field of view, Increased flow and increased pressure

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Table 9-3: Fluid Management Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker CrossFlow
	Single use	Disposable Tubing set	Same
	Shaver Activation Detection	Yes. The Relign Controller integrates fluid management, shaver and RF control into a single unit. Upon activation of the Shaver Handpiece for either RF or motor activation the Controller will activate the appropriate suction level.	Yes. The Stryker Crossflow and the Stryker Crossfire are connected with an independent cable. When the Shaver Handpiece or a Serfas Energy RF probe from the Stryker Crossfire is activated a signal is sent to the Stryker Crossflow to initiate suction from the Stryker Crossflow. In this manner, the independent Stryker Crossflow and Stryker Crossfire controllers work together as a single unit.
	Tubing Cassette	Yes Tubing supplied in dual inflow and outflow tubing cassette	Yes Tubing supplied as individual inflow and outflow tubing cassettes
	Tubing Biocompatibility	Yes	Same
	Tubing Sterilization validation	Gamma Irradiation	Ethylene Oxide

Table 9-4: Combination Shaver Blade Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker Crossfire
Universal product features These features are universal to the three (3)	Shaft Diameter	6.35mm	Stryker 5.5 Barrel Bur: 7.18mm Stryker 5.5 Aggressive Plus: 5.5mm Stryker Serfas Energy 90-S 3.5+: 4.0mm
	Working Length	5”	Same

Table 9-4: Combination Shaver Blade Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker Crossfire
predicate devices	Window positioning	The software positions the window position automatically after release of the activation button/pedal	No window positioning feature
	Aspiration	Aspiration channel for chip removal	Same
	Biocompatibility	Biocompatibility per ISO 10993-1	Same
	Sterilization	Gamma radiation	Ethylene oxide
	Use	Single Use	Same
	Disposable Device	Relign Combination Shaver Blade	Stryker 5.5 Barrel Bur
Bone Burr	Burr diameter	6.35mm	5.5mm
	Number of flutes	3	12
	Burr material	Zirconia	Stainless Steel
	Disposable device	Relign Combination Shaver Blade	Stryker 5.5 Aggressor Plus
Soft Tissue Resection	Cutter diameter	5.5mm	4.5mm
	Number of teeth	5	6
	Cutter material	Zirconia	Stainless Steel
	Disposable device	Relign Combination Shaver Blade	Stryker Serfas Energy Super 90-S 3.5+
RF Ablation and Coagulation	Energy delivered	Bi-Polar Radiofrequency	Same
	Controller compatibility	Relign Controller	Stryker Crossfire
	Shaft diameter	6.35mm	4.0mm
	Working Length	5”	Same
	Electrode material	304 Stainless steel	Tungsten
	Electrode Insulation	Ceramic	Same
	Electrode size	3mm x 1.5mm (oval shape)	2.6mm (round shape)

Table 9-5: Reciprocating RF Probe Comparison			
Function	**Feature**	**Subject Device** Relign Arthroscopic System	**Predicate Device** Stryker Crossfire
	Disposable Device	Reciprocating RF probe	Stryker Serfas Energy 90-S 3.5mm
RF Ablation and Coagulation	Shaft Diameter	4.2mm	4.0mm
	Working Length	5”	Same
	Electrode Positioning	The software positions the electrode automatically after release of the activation button/pedal	No window positioning feature
	Aspiration	Aspiration channel	Same
	Biocompatibility	Biocompatibility per ISO 10993-1	Same
	Sterilization	Gamma radiation	Ethylene oxide
	Use	Single Use	Same
	Energy delivered	Bi-Polar Radiofrequency	Bi-Polar Radiofrequency
	Controller compatibility	Relign Controller	Stryker Crossfire
	Electrode material	304 Stainless steel	Tungsten
	Electrode Insulation	Ceramic	Same
	Electrode size	0.5mm x 2.67mm	2.62mm (round shape)
	Electrode motion	2.75mm of electrode reciprocation in plasma shaver mode	Stationary electrode

10. Conclusions

Relign concludes that based on the results of the Bench Performance, Biocompatibility, Cadaver Studies and Usability Testing, the Relign Arthroscopic System is substantially equivalent to the FDA-cleared predicate devices currently legally marketed in the United States.