December 16, 2022

Rejoni, Inc.
Brian J. Bergeron
VP Engineering
201 Burlington Road
Bedford, MA 01730

Re: K222798
Trade/Device Name: Rejoni Intrauterine Catheter
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: September 19, 2022
Received: September 20, 2022

Dear Brian J. Bergeron:

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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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)*
K222798

Device Name
Rejoni Intrauterine Catheter

Indications for Use *(Describe)*
The Rejoni Intrauterine Catheter is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes.

When used for HSG, the Rejoni Intrauterine Catheter can be used for evaluation of tubal patency.

The Rejoni Intrauterine Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).

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 – K222798

GENERAL INFORMATION

Submission Type:	Traditional 510(k)
Submitter Name:	Rejoni Inc. 201 Burlington Road, Suite 210 Bedford, MA 01730
Contact Person:	Brian J. Bergeron 201 Burlington Road, Suite 210 Bedford, MA 01730 Telephone: (781) 222-0081
Date Prepared:	December 15, 2022
Trade Names:	Rejoni Intrauterine Catheter
Common Name:	Intrauterine Catheter
Regulation Number:	21 CFR 884.4530
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulatory Class:	Class II
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

PREDICATE DEVICE:

Margolin HSG Cannula; Goldstein Sonohysterography Catheter (K180300)

The predicate device has not been subjected to a design-related recall.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Rejoni Intrauterine Catheter is a sterile, single-use, single lumen uterine catheter that facilitates access to the uterus to deliver fluids during Hysterosalpingography (HSG) or Sonohysterography (SHG). The Rejoni Intrauterine Catheter consists of an inner shaft and an additional support sheath over the proximal portion of the catheter shaft to provide additional stiffness. A repositionable stopper ("acorn") is connected to the support sheath, which is placed on the catheter shaft, and can be repositioned from 0 cm up to 10 cm from the distal tip of the catheter. The stopper maintains placement of the catheter against the external cervical os during the procedure, and a luer lock-style adapter on the proximal end is available for compatibility with syringes. The distal end contains a straight through hole for delivery of fluids during the procedure.

INDICATIONS FOR USE

The Rejoni Intrauterine Catheter is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Rejoni Intrauterine Catheter can be used for evaluation of tubal patency. The Rejoni Intrauterine Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS TO THE PREDICATE DEVICE

The intended use and key technological characteristics of the subject and predicate device are compared in the table below

Device Name / **Device Attribute**	**Predicate Device** Goldstein Sonohysterography Catheter **(Legally Marketed: K180300)**	**Proposed Device** Rejoni Intrauterine Catheter **(Subject Device: K222798)**	**Comparison**
Intended Use			

Device Name / Device Attribute	Predicate Device Goldstein Sonohysterography Catheter **(Legally Marketed: K180300)**	Proposed Device Rejoni Intrauterine Catheter **(Subject Device: K222798)**	Comparison
Indications for Use	The Margolin HSG Cannula is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Margolin HSG Cannula can be used for evaluation of tubal patency. The Goldstein Sonohysterography Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).	The Rejoni Intrauterine Catheter is for the delivery of contrast media or saline into the uterine cavity during Hysterosalpingography (HSG) or Sonohysterography (SHG) for examination of the uterus and fallopian tubes. When used for HSG, the Rejoni Intrauterine Catheter can be used for evaluation of tubal patency. The Rejoni Intrauterine Catheter is used to access the uterine cavity for the delivery of saline for Sonohysterography (SHG).	Same
Technology			
Prescription Only	Yes	Yes	Same
Target Patient	Patient undergoing SHG or HSG procedure	Patient undergoing SHG or HSG procedure	Same
Anatomical Site	Uterine cavity	Uterine cavity	Same
Method of Introduction	Introduced into uterine cavity transcervically	Introduced into uterine cavity	Same
Biocompatibility	Surface device, in contact with mucosal tissue, with limited contact (≤ 24h)	Surface device, in contact with mucosal tissue, with limited contact (≤ 24h)	Same

Device Name / Device Attribute	Predicate Device Goldstein Sonohysterography Catheter **(Legally Marketed: K180300)**	Proposed Device Rejoni Intrauterine Catheter **(Subject Device: K222798)**	Comparison
Material	Polytetrafluoroethylene, polyethylene, polyurethane, silicone, black ink	Silicone, polycarbonate, Thermoplastic elastomer	Different: Differences in device materials between the subject and predicate device do not raise different questions of safety and effectiveness (S&E)
Catheter Length	26 or 36 cm	24 cm	Similar
Catheter Shaft Distal Diameter	5.2, 5.3, and 5.4 Fr	2.2 mm (6.6 F)	Different: The subject device is larger in diameter than the predicate device. This difference does not raise different questions of S&E.
Distal Tip Configuration	3 mm single-sided port, closed end	Open distal tip	Different: Differences in placement of fluid outflow openings in the tip of the subject and predicate device do not raise different questions of S&E.
Single Use?	Yes	Yes	Same
Sterility	Ethylene Oxide, Sterility Assurance Level (SAL) of 10^{-6}	Electron Beam SAL of 10^{-6}	Different: The subject and predicate device use different sterilization methods. This difference does not raise different questions of safety and effectiveness.
Shelf Life	3 years	12 months	Different: Different shelf life durations do not raise different questions of S&E.

The indications for use for the subject device and predicate device are identical. Therefore, the intended use is the same (i.e., delivery of contrast medium or saline to the uterine cavity for

HSG and SHG procedures).

Regarding technological characteristics, the subject and predicate device have different designs and dimensions, material composition, shelf life, and sterilization method. The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

PERFORMANCE DATA

The following tests were performed to demonstrate that the Rejoni Intrauterine Catheter met applicable design and performance requirements. All predetermined acceptance specifications were met in the following tests:

Mechanical Testing

The mechanical function and structural integrity of devices were tested to demonstrate that the design specifications from design inputs are fulfilled listed below.

Test Description	Method	Result
Performance - Mechanical	In accordance with device performance specifications	Pass
Performance - Functional	In accordance with device performance specifications	Pass

The following functional and mechanical assessments were performed on the subject device:

- Dimensional Verification
- Visual Assessment
- Tensile Testing (luer to inner shaft; acorn to outer shaft)
- Kink Testing
- Leak Testing

Biocompatibility Testing

Per the indications for use, the Rejoni Intrauterine Catheter is categorized as a surface device contacting mucosal membranes for a limited duration (≤ 24 hours). According to the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* the following endpoints were tested for the subject device:.

Test Description	Method	Result
Cytotoxicity	ISO 10993-5: 2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Pass

Test Description	Method	Result
Sensitization	ISO 10993-10: 2021, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Pass
Intracutaneous Reactivity	ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass

Sterility

The Rejoni Intrauterine Catheter is sterilized via an Electron Beam (E-Beam) process to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated per ISO 11137-1:2006, *Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*, ISO 11137-2: 2013, *Sterilization of health care products – Radiation – Part 2: Establishing the Sterilization Dose*, and ISO 11137-3: 2017, *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control*.

Shelf Life

The Rejoni Intrauterine Catheter has a shelf life of 12-months. Shelf life studies have been conducted to demonstrate that the device maintains its performance (as described in the Mechanical Testing section above) and the packaging will maintain its sterile barrier over the entirety of the intended shelf life. The devices were subjected to environmental conditioning and distribution simulation per ISTA-3A:2018 *Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less* and ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems*. Sterile barrier packaging testing was performed per ISO 11607-1:2019 *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ISO 11607-2:2019, *Packaging for Terminally Sterilized Medical Devices -Part 2: Validation requirements for forming, sealing and assembly processes*.

Following accelerated aging, per ASTM 1980-16 and simulated shipping distribution, the following package integrity tests were completed:

- Bubble leak test per ASTM F2096, *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*;
- Seal strength per ASTM F88/F88M *Standard Test Method for Seal Strength of Flexible Barrier Materials*; and
- Visual inspection

CONCLUSION

The results of the testing described above demonstrate that the Rejoni Intrauterine Catheter is as safe and effective as the predicate device and supports a determination of substantial equivalence.