Hoogland Spine Products, GmbH
Mr. Kenneth K. Kleinhenz, MBA
Principal
QSR Consulting
10807 Dakota Ranch Rd.
Santee, California A92071

Re: K211173
Trade/Device Name: maxmorespine Bipolar Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation devices and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 22, 2022
Received: April 22, 2022

Dear Mr. Kleinhenz:

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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211173

Device Name
maxmorespine® Bipolar Electrodes

Indications for Use *(Describe)*

The maxmorespine Bipolar Electrodes are indicated for the coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator. The maxmorespine Bipolar Electrodes have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

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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Date Prepared: 22 June 2022

I. SUBMITTER

Manufacturer Name:

Hoogland Spine Products, GmbH
Feringastrasse 4
D-85774 Unterfoering
Munich, Germany
+49 34954 247 489 telephone

Mfg. Establishment Registration Number: 3006561161

Official Contact: Mr. Kenneth K. Kleinhenz, MBA
Principal
QSR Consulting
10807 Dakota Ranch Rd.
Santee, CA92071
Telephone (619) 244-9573
Kleinhenz64@gmail.com

II. DEVICE

Name of Device:	maxmorespine Bipolar Electrodes
Common or Usual Name:	Electrosurgical Cutting and Coagulation Devices and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21 CFR 878.4400)
Regulatory Class:	II
Product Code:	GEI

III. PREDICATE DEVICE

joimax Electrosurgical Instruments, K161378

IV. DEVICE DESCRIPTION

Design Characteristics

maxmorespine Bipolar Electrodes are designed with a rounded distal end, an ergonomic handle in various designs and a flat plug connection. The electrodes are sold as one-piece electrodes (1001-BE 003) or consist of a three-piece construction (shaft, electrode and handle). The one-piece electrode and electrodes (1001-BE 002 and 1001-BE 004) are sold as sterile, single-use devices. The handles and shafts (1001-BE 001/H, 1001-BE 001/s and 1001-BE 004/S) are intended for reuse.

The maxmorespine Bipolar Electrodes can be connected to HF electrosurgical generators that have the permissible Vp voltage via a flat plug using the standard bipolar connection cables. The maxmorespine Bipolar Electrodes consist of the following electrodes and accessories:

1001-BE 001/H	Bipolar Forceps Handle for Flexible Electrodes with Flat-Plug
1001-BE 001/S	Shaft for Bipolar Forceps Handle for Flexible Electrodes, Long
1001-BE 002	Bipolar Coagulation Electrode, Flexible, Long
1001-BE 003	Bipolar Coagulation Electrode
1001-BE 004/S	Shaft for Bipolar Forceps Handle for Flexible Electrodes, Short
1001-BE 004	Bipolar Coagulation Electrode, Flexible, Short

The following products are provided sterile. They are sterilized by ethylene oxide sterilization:

1001-BE 002	Bipolar Coagulation Electrode, Flexible, Long
1001-BE 003	Bipolar Coagulation Electrode
1001-BE 004	Bipolar Coagulation Electrode, Flexible, Short

The following products are reusable:

1001-BE 001/H	Bipolar Forceps Handle for Flexible Electrodes with Flat-Plug
1001-BE 001/S	Shaft for Bipolar Forceps Handle for Flexible Electrodes, Long
1001-BE 004/S	Shaft for Bipolar Forceps Handle for Flexible Electrodes, Short

V. INDICATIONS FOR USE

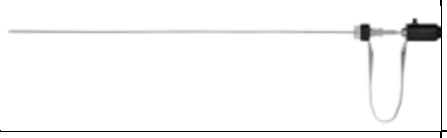
The maxmorespine Bipolar Electrodes are indicated for the coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator. The maxmorespine Bipolar Electrodes have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The maxmorespine Bipolar Electrodes shares indications for use and design principles with the predicate device: joimax Electrosurgical Instruments predicate device (K161378); a Class II medical device that was cleared for marketing in the United States under K161378. The design principles of the maxmorespine Bipolar Electrodes device and the joimax Electrosurgical Instruments predicate device (K161378) are substantially equivalent, consisting of sterile, single use, detachable, flexible electrodes of various lengths, reusable stainless steel guide cannula / shaft that facilitates the flexible electrode to pass through the shaft of the cannula, and a reusable handle that attaches to the guide cannulas on one end and the generator on the opposite end. The subject device and the predicate device also share the same design feature a detachable electrode and cannula / shaft that mount to the handle; both designs allowing for the use of various electrode lengths depending on the physician's needs / surgical approach. Furthermore, the maxmorespine Bipolar Electrodes device and the joimax Electrosurgical Instruments (K161378) predicate device share substantially equivalent design principals of providing a single use, sterile, 'pencil' design in which the electrode is permanently mounted on a fixed male fitting that plugs into the handle; which is connected to a generator that provides power to the electrode.

The maxmorespine Bipolar Electrodes are substantially equivalent to the joimax Electrosurgical Instruments predicate device (K161378) in the following respects:

	Subject Device	**Predicate Device**
	maxmorespine Bipolar Electrodes	**joimax Electrosurgical Instruments (K161378)**
Indications for Use	The maxmorespine Bipolar Electrodes are indicated for the coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator. The maxmorespine Bipolar Electrodes have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.	The joimax Electrosurgical Instruments are indicated for the coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator. The joimax Electrosurgical Instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.
Mode of Operation	Bipolar	Bipolar
Mechanics of Action	Coagulation	Coagulation

	Subject Device	**Predicate Device**
	maxmorespine Bipolar Electrodes	**joimax Electrosurgical Instruments (K161378)**
Activation Method	Footswitch	Footswitch
Trade Names	- Bipolar Forceps Handle - Shaft for Bipolar Forceps Handle - Bipolar Coagulation Electrode, Flexible	- Vaporflex Handle - Vaporflex Shaft - Vaporflex Probe, Bipolar, Ball Tip
Design		
Reusable Handle and Shaft	Yes	Yes
Sterile, Single-Use Electrode	Yes	Yes
Flexible Tip	Yes	Yes
Shaft Diameter	2.3mm	2.75mm
Shaft Lengths	272mm / 408.8mm	250mm / 275mm/ 320mm
Electrode Lengths	363.2mm / 500mm	250mm / 275mm / 320mm
Maximum output voltage	250 Vp	1200 Vp
Product Code	GEI	GEI
Regulation Number	878.4400	878.4400

	Subject Device	**Predicate Device**
	maxmorespine Bipolar Electrodes	**joimax Electrosurgical Instruments (K161378)**
Trade Names	- Bipolar Coagulation Electrode	- Legato Probe, Bipolar, Ball Tip 270 - Legato Handpiece bipolar
Image		
Sterile, Single-Use Electrode	Yes	Yes
Sterilization Method	Ethylene oxide (EO)	Ethylene oxide (EO)
Flexible Tip	Yes	Yes
Shaft Diameter	1.35mm	2.0mm
Shaft Length	377mm	270mm
Product Code	GEI	GEI
Regulation Number	878.4400	878.4400

VII. PERFORMANCE DATA

Non-Clinical Data

Biocompatibility Testing

The patient contact materials were evaluated against the international standard ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Guidance Document entitled, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process". The following biocompatibility tests were considered:

Cytotoxicity
Sensitization
Irritation
Pyrogenicity

Electrical Safety
Electrical safety and EMC testing were conducted on the maxmorespine Bipolar Electrodes device, consistent with the appropriate sections of the following electrical standards: IEC 60601-1:2012 Medical electrical equipment - Part 1-General requirements for basic safety and essential performance, IEC 60601-2-2:2017, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Sterilization
Successful sterilization validation testing was conducted according to the ISO 11135. Tests were performed on the residues of ethylene oxide (EO). The validation target of a sterilization acceptance level (SAL) of 10^{-6} was achieved.

Packaging Validation
Testing of the primary packaging for the maxmorespine Bipolar Electrodes was successfully conducted according to ISO 11607-1.

Software Verification and Validation
The maxmorespine Bipolar Electrodes do not contain software.

Tissue Performance Testing
The performance of the maxmorespine Bipolar Electrodes have been evaluated with tissues of various density (muscle, kidney, and liver) and have been shown to be substantially equivalent to the predicate device.

VIII. CONCLUSIONS
Performance testing on various tissue types (muscle, kidney, liver) has demonstrated that the performance of the maxmorespine Bipolar Electrodes are substantial equivalent to the predicate device (K161378). The nonclinical testing demonstrate that the subject device is safe and substantially equivalent to the predicate device. The performance testing and non-clinical testing demonstrate that the maxmorespine Bipolar Electrosurgical Instruments are substantially equivalent to the predicate device and do not raise new questions regarding the safety and effectiveness as compared to the predicate device (K161378).