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

June 18, 2016

Vitalitec Medizintechnik GmbH
% Ms. Lynette Howard
President
Lyle Howard Corporation
106 East 5th Avenue
Mount Dora, Florida 32757

Re: K152734
Trade/Device Name: Vitalitec Kerrison Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: May 17, 2016
Received: May 20, 2016

Dear Ms. Howard:

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 yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K152734

Device Name
Vitalitec Kerrison Rongeurs

Indications for Use *(Describe)*
Vitalitec Kerrison Rongeurs are manually operated reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.

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

Device Submitter

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Contact Person: Lynette Howard
Date Prepared: June 16, 2016

Establishment Registration Number: 8044057

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: Vitalitec Kerrison Rongeurs
Common Name: Kerrison Rongeurs
Classification Name: Class II, 21 CFR 882.4840, Product Code: HAE

Predicate Device [21 CFR 807.92(a)(3)]

For this submission, Vitalitec Medizintechnik GmbH has chosen the Integra LifeSciences Corporation device, Integra™ Kerrison Rongeurs, cleared under 510(k) K092227.

The Integra LifeSciences Corporation rongeur is a class II device according to 21 CFR 882.4840, Product Code HAE.

Description of the Device [21 CFR 807.92(a)(4)]

The Vitalitec Medizintechnik GmbH Kerrison Rongeur is a class II device according to 21 CFR 882.4840, Product Code HAE.

The Vitalitec Medizintechnik GmbH Kerrison Rongeurs are reusable stainless steel instruments that are sterilizable and packaged non-sterile. Devices are available with the following features: 1-6 mm bite sizes; 14 mm – 16 mm jaw openings; 40° and 90° up/down cutting angles; regular and thin footplates; various handle and shaft styles; sliding shaft; detachable.

A rongeur is a robust constructed reusable surgical instrument with sharp, spoon shaped working ends, which used for cutting or biting bone during surgery involving the skull or spinal

column.In Neurosurgery a rongeur is used for grasping and dissecting of bone and tissue during neurosurgical and orthopedic procedures.

Indications for Use

Vitalitec Kerrison Rongeurs are manually operated reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.

Technological Characteristics [21 CFR 807.92(a)(6)]
The subject device is similar in design, indications for use, and mechanical performance to the predicate device.

Characteristic	Subject	Predicate
510(k) #	K152734	K092227
Class	II	II
Product Code	HAE	HAE
Regulation #	882.4840	882.4840
Classification Name	Manual, Rongeur	Manual, Rongeur
Trade Name	Vitalitec Kerrison Rongeurs	Integra™ (Jarit®, Ruggles™, R&B Redmond™, (Redmond™), Miltex®, MeisterHand®) Kerrison rongeurs
Indications for Use	Vitalitec Kerrison Rongeurs are manually operated reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.	Integra™ (Jarit®, Ruggles™, R&B Redmond™, (Redmond™), Miltex®, MeisterHand®) Kerrison rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.
Materials – Patient Contact – Transient Use	Handle, Shaft, Jaw Parts: Stainless steel 1.4021 (420 SS) composition X20Cr13 according to DIN EN ISO 7153-1 Surface Coating: Titanium-aluminium-nitride coating (TiAIN)	420 Stainless steel Surface Coatings: Titanium-Diamond coat & Hard coat™-nitride coating (TiAIN); Titanium Nitride (TiN); Stealth coat & Smooth-coat™ (Dicronite DL-5); Ultra-coat™ (ZrN); PTFE (polytetrafluoroethylene (Teflon®); Silicon (Elastosil® LR3003/80 A,B)
Packaging	Shipped non-sterile	Shipped non-sterile
Type of Device	Reusable Surgical Instrument	Reusable Surgical Instrument

Characteristic	Subject	Predicate
510(k) #	K152734	K092227
Class	II	II
Product Code	HAE	HAE
Regulation #	882.4840	882.4840
Classification Name	Manual, Rongeur	Manual, Rongeur
Sterility	Sterilizable	Sterilizable
Utility	Reusable	Reusable
Technological Principles	Rongeurs (Kerrisons) are manual surgical instruments constructed with a scoop-shaped cutting tip which also compresses and cuts bone.	The only difference is that the upper slide of the Integra moves upward, where the Vitalitec upper shaft moves sideways to detach for cleaning.
Elements	Instrument body, movable handle to activate jaws, scoop shaped cutting tip.	Instrument body, movable handle to activate jaws, scoop shaped cutting tip.

The Vitalitec Medizintechnik GmbH Kerrison Rongeur is substantially equivalent to the predicate device since the basic features and the intended uses are the same. The only difference in design between the predicate is that the upper slide of the Integra moves upward, where the Vitalitec upper shaft moves sideways to detach for cleaning. The predicate device is available with additional coatings that are not used by Vitalitec. The minor differences between the Vitalitec Medizintechnik GmbH Kerrison Rongeur and the predicate device raise no new issues of safety and effectiveness. These differences have no effect on the function or intended use of the device.

Performance Data [21 CFR 807.92(b)(1)]

The Vitalitec Medizintechnik GmbH Kerrison Rongeurs have been successfully tested for its functions, performance, and safety as per FDA recognized standards including:

Recognition Number 14-295: AAMI / ANSI ST81:2004/(R)2010, sterilization of medical devices - information to be provided by the manufacturer for the processing of resterilizable medical devices. (Sterility)

Recognition Number 5-40: ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

Recognition Number 5-90: ISO 15223-1 Second Edition 2012-07-01, medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements. (General I (QS/RM))

Recognition Number 2-156: AAMI / ANSI / ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

Recognition Number 8-344: ISO 7153-1 Second edition 1991-04-01, surgical instruments -- metallic materials -- part 1: stainless steel [including: amendment 1 (1999)]. (Materials)

Recognition Number 14-333: ISO 17665-1 First edition 2006-08-15, sterilization of health care products - moist heat - part 1: requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)

Test	Test Method Summary	Results
Mechanical Testing Cutting performance testing/bite force	Mechanical testing was performed to compare functional requirements of the Vitalitec Kerrison Rongeurs with the predicate device. Cutting of control carton 250g/m2 according to DIN 58298 using both the predicate and proposed Kerrison Rongeur.	100% Inspection resulted in all samples of both the predicate and the proposed Kerrison Ronguers meeting the requirements of DIN 58298, resulting in the determination of substantial equivalence. Test showed the measured functional specifications of the Vitalitec Kerrison rongeurs were equivalent or better than comparable specifications of the predicate device.

Reprocessing:

Vitalitec Medizintechnik GmbH Kerrison Rongeurs cleaning and disinfection validations studies were performed in accordance with FDA Draft Guidance : Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (May 2, 2011) The subject device is shipped non-sterile and is intended to be sterilized by user.

Clinical Data [21 CFR 807.92(b)(2)]

Clinical data was not used to determine substantial equivalence.

Conclusion [21 CFR 807.92(b)(3)]

Substantial equivalence for this device is based on similarities in intended use, function (design and technology), performance, and operational principle to the predicate device, Integra Kerrison Rongeurs (K092227).

The Vitalitec Medizintechnik GmbH Kerrison Rongeurs intended use and indications for use is identical to the Integra Kerrison Rongeurs (K092227) for cranial and spine applications: Neurosurgery.

The material used for the Vitalitec Medizintechnik GmbH Kerrison Rongeur is the same material as used for the Integra predicate Rongeur. The only difference is that the Integra devices have additional coating materials that are not used by Vitalitec.

The design, operational principle and technology of cutting bone are identical to Integra predicate Rongeurs. The material is captured and removed the same as the predicate device. The mechanical cut of the Vitalitec Medizintechnik GmbH Kerrison Rongeur is identical to the predicate. The only technological difference is that the upper slide of the Integra moves upward, where the Vitalitec upper shaft moves sideways to detach for cleaning. This does not impact the intended use of the device.

Based on predicate analysis as well as non-clinical performance testing, Vitalitec Medizintechnik GmbH has demonstrated the subject device is identical to the predicate in performance based on intended use. The results of the testing confirmed that Vitalitec Medizintechnik GmbH Kerrison Rongeurs and Integra Kerrison Rongeurs performed as intended.

Due to the similarity of the intended use, indications of use, function, materials, performance, and operational principle to the predicate device, Vitalitec Medizintechnik GmbH believes that the Vitalitec Medizintechnik GmbH Kerrison Rongeur does not raise any new safety or effectiveness issues.