DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 24, 2016

K2 Medical GmbH & Co. KG
Mr. Harald Jung
Manager Quality & Regulatory
Unter Buchsteig 5
Tuttlingen, Baden-Wuerttemberg 78532
Germany

Re: K150468
Trade/Device Name: Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: February 25, 2016
Received: February 26, 2016

Dear Mr. Jung:

This letter corrects our substantially equivalent letter of February 29, 2016.

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 FDA

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)*
K150468

Device Name
Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs

Indications for Use *(Describe)*
Laminectomy Rongeurs, Kerrison Rongeurs and IVD Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column in patients two years of age or older.

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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510(k) Summary

1. Submitter Information

Submitter:	K2 Medical GmbH & Co. KG Unter Buchsteig 5 D-78532 Tuttlingen GERMANY
Contact Person:	Harald Jung, Manager Quality & Regulatory Phone: +49 7462 94799-182 Fax: +49 7462 94799-282
Date Prepared:	12.02.2015
Device Trade Name:	K2 Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs
Common / Usual Name:	Laminectomy Rongeurs, Kerrison Rongeurs and IVD Rongeurs
Classification Name	Rongeur, Manual (21 CFR 882.4840)
Regulatory Class:	II
Product Code:	HAE

2. Predicate Device:

Trade name	Integra™ Kerrison Rongeurs	Instrumed Rongeur
510(k) No.	K092227	K081651
510(k) submitter / holder	Integra LifeSciences Corporation 311 Enterprise Drive Plainsboro, NJ 08536 USA	INSTRUMED INTERNATIONAL, INC. 626 Cooper Court Schaumburg, IL 60173

3. Device Description:

K2 Laminectomy Rongeurs, Kerrison Rongeurs and IVD Rongeurs (Intervertebral Disk Rongeurs) are reusable manual stainless steel instruments. They are sold unsterile and can be reprocessed (cleaned and sterilized) according the instructions for use.

The devices are available with the following features:

Kerrison style Rongeur with a fixed and a sliding shaft and an angled footplate
- with different handles (Micro Handle, Spurling Handle, Cherry handle, Ferris-Smith handle, Tarpon handle)
- with different surface treatments (mirror finish, satin finish, matt/dull finish, brush-finished and different coatings (ceramic, black, gold)
- different shaft overall length (6 “ inch to 15 “ inch)
- different sizes (1mm to 6 mm)
- different angles (up 40°, up 90°, down 90°
- without ejector or with different types of ejectors
- with straight shaft, curved (Foraminotomy style) or with Bayonet Shaft,
- traditional style or with special cleaning channel
- traditional style or with opening mechanism (convertible, take-apart)
- with rotating shaft angled 90° and 40°

IVD Rongeurs (Intervertebral disk Rongeurs) with one fixed shaft, one sliding shaft and a hinged mouthpart

- in different styles: Decker Forceps, MIS* Rongeurs/Micro-Pituitary, MIS* Cushing Rongeurs, Spence iVD Rongeurs, Poppen IVD Rongeurs, Peapod IVD Rongeurs, Love-Gruenwald, Selverstone Rongeurs, Williams Dissecting Forceps, Spurling IVD Rongeurs, Sypert Rongeur, Wilde IVD Rongeurs, Hoen IVD Rongeurs, Oldberg Disc Rongeur, Jackson IVD Rongeurs, Schlesinger IVD Rongeurs, Caspar type Rongeur, Schlesinger Rongeur (MIS* Minimally Invasive Surgery)
- with different length and jaw sizes
- angled and straight
- with closed jaw and with fenestrated jaws
- with smooth jaw and with teeth

Laminectomy Rongeurs with double action joints and strong handle

- Fulton Laminectomy Rongeurs

4. Indications for Use

Laminectomy Rongeurs, Kerrison Rongeurs and IVD Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column in patients two years of age or older.

5. Comparison of technological Characteristics to predicate device

	new device	predicate Integra K092227	predicate Instrumed K081651
indication for use and target population	Laminectomy Rongeurs, Kerrison Rongeurs and IVD Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column in patients two years of age or older.	Integra™ Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	The intended use of Instrumed Rongeur is to access, cut and bite soft tissue and bone during surgery involving the spinal column.
design	Kerrison style Rongeur with a fixed and a sliding shaft and an angled footplate IVD Rongeurs with one fixed shaft, one sliding shaft and a hinged mouthpart Laminectomy Rongeurs with double action joints and strong handle	same	same
design	Kerrison Rongeur with cleaning channel	without cleaning channel	same
design	Kerrison Rongeur with pushbutton opening mechanism and with lever opening mechanism	Kerrison Rongeur with lever opening mechanism	Kerrison Rongeur with lever opening mechanism
Materials / Biocompatibility	Stainless Steel AISI 420 A Titanium acc. ASTM F136 / ISO 5832-3 several surface coatings: anthracite, gold, black silicone coated handle	Stainless Steel several decorative coatings (Diamond, Stealth)	Stainless Steel Titanium same same
Cleaning	Instruments can be processed in a validated washer-disinfector prior to sterilization.	same	same
Sterilization	non-sterile Sterilization prior to use, using steam sterilization.	same	same

6. Testing

Performance data

The following performance data were provided in support of the substantial equivalence determination:

Test	Test Method Summary	Results
Automatic Reprocessing Validation "Panther Kerrison Rongeur" + Amendment to Automatic Reprocessing Validation "Panther Kerrisson Rongeur.	The test was performed to verify that the devices could be cleaned with the provided cleaning steps in the IFU. This test method is performed by contamination of accessible, interior, and exterior surfaces of instruments intending to reach the sites identified as the least accessible or most difficult to reach sites (worst case). According AAMI TIR 30, the effectiveness of the reprocessing cycle is evaluated by comparing visible contamination (red blood cells), residual protein, the number of organisms and TOC level recovered from the control instruments and the test instruments.	This validation provides evidence that viable microbiological contamination as well as a soil contamination of the "Panther Kerrison Rongeur" are removed by the given cleaning and disinfection instructions
Sterilization testing	The test is to verify that the devices could be sterilized with the provided sterilization procedure described in the IFU. The test specimens were contaminated with bioindicators or with a challenge suspension and were tested for sterility after the sterilization process. To assure a SAL of 10^-6 only a part cycle of the recommended sterilization process was performed in validation.	A reduction of test bacteria was observed and assured showing that contaminated test specimens are free of viable/augmentable bacteria after sterilization.
Boiling Test	This test is to verify the corrosion resistance of the instruments. It is performed according ASTM F1089-10 section 6.1. Devices are boiled in distilled water for 30 min, cooled down in the water for 3 h and dried at air for 2 h. Devices were not allowed to show signs of corrosion.	The tested instruments did not show any signs of corrosion.
Cytotoxic testing	Test is to show, that no toxic residuals from manufacturing remained on the device. The test was performed with finished devices from all the different materials and coatings according ISO 10993-5. Devices must be considered non cytotoxic.	All the tested samples were considered to be NON CYTOTOXIC.
Irritation testing	The objective of this study was to determine if device-extracts produced an irritation reaction when injected intracutaneously in rabbits. Test was performed according ISO 10993-10 with finished devices in all material-coating configurations. Devices were extracted in 0.9 % saline and cottonseed Oil for 72 h. Extracts were injected intracutaneously and site was graded for tissue reaction at 24, 48 and 72 hours after dose administration. Skin irritation was evaluated according ISO 10993-10.	Test data indicated that the device extracts did not cause a skin irritation reaction.
Mechanical testing - handle force - bite force - extended use	Mechanical tests were performed to compare functional requirements of the K2 Rongeurs with the predicate devices. Therefore the handle force for actuating the device was measured as well as the force to cut artificial bone material. Further on the cutting force and cutting size of new instruments was measured and compared to worn out instruments with the artificial bone material. Devices has to perform similar or better than predicate devices.	Test showed that the measured functional specifications of the K2 Rongeurs were equivalent or better than the comparable specifications of the predicate devices.

The nonclinical testing demonstrated, that the K2 Rongeur is substantial equivalent to the predicate device and performs as well as or better than the legally marketed predicate devices.

7. Substantial Equivalence

Substantial equivalence for the K2 Rongeurs is based on similarities in intended use, design (function, dimensions, operational principles and performance tests), materials and labeling based on their promotional materials, labeling and clearance letter.

The only difference to the predicate devices is another opening mechanism with a push button for the K2 Kerrison Rongeurs. By pressing the push button the upper part of the shaft can slide back and is released from the guide of the lower part. It can easily be opened for cleaning.
After cleaning the upper part is laid down to the lower part and snapped in by pressing the handle.

The predicate device from Integra and from Instrumed has a lever to release the upper part from the guide of the lower part.

The minor technological differences between the K2 Rongeurs and the predicate devices raise no new issues of safety or effectiveness.
Performance data demonstrate, that the K2 Rongeurs do comply to relevant standards and that their main functional features are equivalent to the predicate devices from Integra and Instrumed.
Thus, the K2 Rongeur is substantially equivalent to the predicate device.