June 3, 2022

KLS-Martin L.P.
Susan Leander
Regulatory Affairs Project Supervisor
11201 Saint Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K210741
Trade/Device Name: KLS Martin Neuro Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: May 2, 2022
Received: May 3, 2022

Dear Susan Leander:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K210741

Device Name
KLS Martin Neuro Rongeurs

Indications for Use *(Describe)*
KLS Martin Neuro 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.

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510(k) Summary

K210741

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Susan Leander Regulatory Affairs Project Supervisor Phone: 800-625-1557 Email: susan.leander@klsmartinusa.com
Alternate Correspondent:	Melissa Bachorski Assistant Director, RA/QMS Phone: 800-625-1557 Email: regaffairs@klsmartin.com
Date Prepared:	May 31, 2022
Trade Name:	KLS Martin Neuro Rongeurs
Common Name:	Manual Rongeur
Classification Name:	Manual Rongeur (21 CFR 882.4840)
Regulatory Class:	II
Product Code:	HAE
Predicate Device:	K-2 Medical GmbH & Co. KG **(K150468)** Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs
Reference Device:	INSTRUMED INTERNATIONAL, INC.**(K081651)** Instrumed Rongeur

Device Description

The KLS Martin Neuro Rongeurs are manual, reusable, stainless-steel instruments. They are provided non-sterile and must be cleaned and sterilized by the end user before use. Validated methods are provided in the instructions for use that accompany each device. The instruments are available coated or uncoated in a variety of styles, with options for a range of cutting angles, shaft lengths and profiles, jaw widths, and handle designs. Additionally, the KLS Martin Neuro Rongeurs can have a push button opening mechanism to allow separation of the long shafts allowing for improved cleaning and sterilization.

Indications for Use

The KLS Martin Neuro 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 and older.

Technological Characteristics & Substantial Equivalence Discussion

The subject device, KLS Martin Neuro Rongeurs, is comparable in materials, design, composition, and function to the predicate device, K150468. The only differences are in some of the options available, such as cutting angles and shaft lengths. The subject device has jaw widths ranging from 1 mm to 6 mm, which is the same as the predicate device. The subject devices have cutting angles that are equivalent to those of the predicate and reference devices. Cutting angles range from 30° to 90° and can angle up or down. The selection of cutting angles allow for greater accessibility to the surgical site. Shaft lengths range from 6 to 15 inches for the predicate device and from 15 to 30 cm (~6 to ~12 inches) for the subject device. Rongeurs are multipurpose instruments that can be used in a variety of applications to cut and bite bone for access to underlying tissue. All of these options are surgeon's preference and do not raise new questions of safety or effectiveness of the instruments.

	KLS Martin Neuro Rongeurs (K210741)	K2 Medical(K150468) Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs	Medline (Instrumed) Rongeurs (K081651)
	Subject Device	**Primary Predicate**	**Reference Device**
Indications for Use	The KLS Martin Neuro 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.	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.	The intended use of Instrumed Rongeur is to access, cut and bite soft tissue and bone during surgery involving the spinal column.
Contraindications	No known contraindications	None specified.	None specified.
Rx or OTC	Rx	Rx	Rx
Single Use or Reusable	Reusable	Same	Same
Opening mechanism	Push button	Same	Same
Classification	21 CFR 882.4840 Class II	21 CFR 882.4840 Class II	21 CFR 882.4840 Class II
Product Code	HAE	HAE	HAE
Material	Stainless steel 1.4021/X20Cr13/AISI 420A 1.4305/X8CrNiS18-9/AISI 303 1.4310 /X10CrNi18-8/AISI 301 TiAlN coating (Solid Black option) Gold plating	Stainless Steel AISI 420 A Titanium acc. ASTM F136 / ISO 5832-3 several surface coatings: anthracite, gold, black silicone coated handle	Not stated.
Cleaning	Must be cleaned following a validated method before each use	Same	Same

	KLS Martin Neuro Rongeurs (K210741)	K2 Medical(K150468) Laminectomy Rongeurs, Kerrison Rongeurs, IVDRongeurs	Medline (Instrumed) Rongeurs (K081651)
	Subject Device	**Primary Predicate**	**Reference Device**
Sterilization	Non-sterile Must be sterilized following a validated method before each use	Same	Same
Anatomical Sites	Spine & cranium	Same	Spine
Use Environment	Sterile OR	Same	Same
User	Professional users: The instruments may be used only by surgical specialists. Reprocessing must be performed accordingly by trained and qualified personnel of the reprocessing unit for medical devices.	Same	Same

Performance Testing – Non-clinical

Performance Testing

KLS Martin Neuro Rongeurs were evaluated for corrosion and heat resistance. Comparative testing was completed versus the reference device, the Medline (Instrumed) Rongeurs (K081651).

Performance Testing

Test Name	Test Description	Result
Autoclave Test	Test to verify corrosion resistance during autoclaving.	No corrosion detected
Boiling Test	Test to verify corrosion resistance of instruments.	No corrosion detected
Copper Sulfate Test	Test to verify corrosion resistance of instruments.	No corrosion detected
Thermal Test	Test to verify thermal resistance of instruments.	No corrosion detected
Cut Quality	Compare cut quality	Smooth cuts achieved, pass

Comparative Functional Testing

Test Name	Test Description	Result
Spring Force	Compare spring force	Comparable to reference device
Cut Force	Compare cut force	Comparable to reference device
Push Button Force	Compare push button force	Comparable to reference device

Biocompatibility Testing

Biocompatibility endpoints were evaluated in accordance with ISO 10993. Biocompatibility testing for chemical characterization of leachables/extractables, cytotoxicity, sensitization, irritation, material mediated pyrogenicity and hemocompatibility. Test results indicate that the KLS Martin Neuro Rongeurs are biocompatible.

Sterilization Testing

Steam sterilization validations were performed using the dynamic-air-removal cycle in accordance with AAMI ANSI ISO 17665-1 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. All test method acceptance criteria were met.

Performance Testing – Clinical

Clinical testing was not necessary for the substantial equivalence determination.

Substantial Equivalence Conclusion

KLS Martin Neuro Rongeurs are comparable in materials, design, composition, and function to the predicate and reference devices, K150468, K2 Medical Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs and K081651, Medline (Instrumed) Rongeurs. They have the same intended use, same fundamental principles of operation, and same technological features as the predicate device. The KLS Martin Neuro Rongeurs are substantially equivalent to the predicate device.