June 29, 2023

Aesculap, Inc.
Benjamin Oswald
Global Regulatory Affairs
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K223596
Trade/Device Name: SQ.line KERRISON
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: June 1, 2023
Received: June 1, 2023

Dear Benjamin Oswald:

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 -S
Digitally signed by Adam D. Pierce -S
Date: 2023.06.29 17:23:17 -04'00'

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.

Submission Number *(if known)*

K223596

Device Name

SQ.line KERRISON

Indications for Use *(Describe)*

The SQ.line KERRISONS (bone punches) are manually operated instruments indicated 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K223596

510(k) Summary

Prepared on: 2023-06-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Aesculap, Inc.
Applicant Address	3773 Corporate Parkway Center Valley PA 18034 United States
Applicant Contact Telephone	+4974619531061
Applicant Contact	Mr. Benjamin Oswald
Applicant Contact Email	benjamin.oswald@aesculap.de

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SQ.line KERRISON
Common Name	Manual rongeur
Classification Name	Rongeur, Manual
Regulation Number	882.4840
Product Code	HAE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153243	Fehling Punches	HAE

Device Description Summary

21 CFR 807.92(a)(4)

The SQ.line KERRISON bone punches are reusable surgical instruments made out of stainless steel. The devices are coated with Medthin™ 42 DLC. The bone punches are available with the following features:
shaft lengths 180 - 280 mm, bite sizes 1 - 6 mm, jaw openings 10 - 15 mm, cutting angles 90° and 130° up/down, standard and thin profile footplates and semi-detachable or fully detachable with an ejector.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SQ.line KERRISONS (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The SQ.line KERRISON bone punches have the same indication for use as the predicate Fehling Punches.

Technological Comparison

21 CFR 807.92(a)(6)

The SQ.line KERRISON bone punches are substantially equivalent to the predicate Fehling Punches. The subject device intended use, design and principle of operation are the same as of the predicate device. The SQ.line KERRISON bone punches are manufactured from similar materials as the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

A cutting test was performed to evaluate the cutting edge lifetime of the SQ.line KERRISON after 25,000 cuttings performed. The test performed confirmed the acceptance criterias were met.

A performance test was done in order to evaluate the force needed on the handle of the SQ.line KERRION to cut. The test performed showed that the applied force meets the acceptance criteria.

The mechanical performance was assessed after reprocessing and met the acceptance criteria.

Biocompatibility:
Biocompatibility endpoints were evaluated in accordance with ISO 10993. Biocompatibility testing for chemical characterization of leachables/extractables, cytotoxicity, sensitization,
irritation and acute systemic toxicity. Test results indicate that the SQ.line KERRISONS are biocompatible.

Animal and Clinical Testing:
No animal or clinical testing was necessary for determination of substantial equivalence.

Clinical testing is not applicable.

Both performance tests show that the SQ.line KERRISON performs substantially equivalent to the predicate device and do not raise new questions regarding safety and effectivness.