July 21, 2020

Ace Medical
% Cassandra Petrov
Regulatory Engineer
JALEX Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K200387
Trade/Device Name: Ace Medical Surgical Instruments
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE, HTX
Dated: June 15, 2020
Received: June 19, 2020

Dear Cassandra Petrov:

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
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Adam D. Pierce, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200387

Device Name
Ace Medical Surgical Instruments

Indications for Use *(Describe)*
The Ace Medical Surgical Instruments 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

Submitted By:	Ace Medical Co. 2230 Park Ave. #202 Cincinnati, OH 45206
Date:	July 21, 2020
Contact Person:	Cassandra Petrov, Regulatory Engineer
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Device Trade Name:	Ace Medical Surgical Instruments
Device Classification Name:	882.4840 Manual Rongeur, 888.4540 Orthopedic Manual Surgical Instrument
Device Classification:	Class II , Class I
Reviewing Panel:	Neurology, Orthopedic
Product Code:	HAE, HTX
Predicate Device:	Fehling Punches (K153243) Integra Kerrison Rongeurs (K150428) The predicate device has never been subject to recall.

Device Description:

The Ace Medical Surgical Instruments are manufactured from 420 and 304 stainless-steel conforming to ASTM F899. Instruments are available in both Stainless Steel and Titanium Aluminum Nitride (AlTiN) coated Stainless Steel configurations. They are packaged non-sterile and can be reprocessed per the instructions for use. Surgical instruments consist of Kerrison and Pituitary Rongeurs, and are available in numerous sizes and configurations including:

- Different handles (Large, Standard, for use with Rotating Shafts)
- Different shaft lengths (6-14 inches)
- Different Bite Sizes (0.5-6 mm)
- Different Angles (40° and 90°, up and down)
- Different Footplates (Standard, Thin and Ultra-Thin)
- With or without ejector
- Different shaft styles (Standard, Bayonet, Rotating, Endoscopic, Detachable, Curved)

Intended Use:

The Ace Medical Surgical Instruments are manually operated, reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.

Summary of Technological Characteristics:

The Ace Medical Surgical Instruments are identical to the predicate as they are manufactured by the same company, have the same intended use and the same fundamental scientific technology. Both devices are identical in several aspects which are summarized in the table below. A more detailed comparison of the Ace Medical Surgical Instruments with predicate and reference predicate devices is included in this submission.

Table 1. Technological Characteristics Comparison

Item	Ace Medical Instruments	Fehling Punches	Integra Kerriosn Rongeurs	Equivalence
Intended Use	The Ace Medical Surgical Instruments are manually operated, reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.	Manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column	Manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column	Equivalent
Manufacturer	Gebruder Zepf Medizentechnik GmbH & Co. KG	Gebruder Zepf Medizentechnik GmbH & Co. KG	Unknown	Equivalent
Design	Rongeur with a fixed and a sliding shaft and angled footplate	Rongeur with a fixed and a sliding shaft and angled footplate	Rongeur with a fixed and a sliding shaft and angled footplate	Equivalent
Design Features	Manual, non-electrical, non-sterile, reusable, non-malleable	Manual, non-electrical, non-sterile, reusable, non-malleable	Manual, non-electric, reusable, non-malleable	Equivalent
Materials	420 and 304 Stainless Steel (ASTM F-899), Surface Coating-CERAMO® (TiAIN); Silicone	420 and 304 Stainless Steel (ASTM F-899), Surface Coating-CERAMO® (TiAIN); Silicone	420 Stainless steel	Equivalent

Verification and Validation Testing:

Test	Test Summary	Result
Mechanical Strength	The Fehling Punches (predicate) were subject to static and dynamic mechanical testing to demonstrate fatigue resistance	The subject device is identical to the predicate in materials, manufacture, design, and

	and cutting displacement in relation to force applied.	function. No further mechanical testing was conducted.
Cleaning	A cleaning validation was performed on worst case instrument per the process provided in the IFU.	Instruments were free of visible soil and met acceptance criteria for protein and hemoglobin content per AAMI TIR 30:2011.
Sterilization	A steam sterilization validation was performed using the half cycle approach.	Sterilization parameters will provide a sterility assurance level of 10^{-6}.
Biocompatibility	The predicate device was deemed biocompatible. The subject device is identical to the predicate in materials, manufacturing processes, manufacturer, sterilization, and technical specifications.	No further biocompatibility testing is required.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.