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

August 4, 2016

Fehling Instruments GmbH & Co. KG
% Mr. Arne Briest
CEO
VISAMED GmbH
Kastellstr. 8
Karlsruhe D-76227
Germany

Re: K153243
Trade/Device Name: Fehling Punches
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: July 4, 2016
Received: July 6, 2016

Dear Mr. Briest:

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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.08.04 15:18:14 -04'00'

for 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)*
K153243

Device Name
Fehling Punches

Indications for Use *(Describe)*
Fehling rongeurs (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.

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510(k) Summary

1. Submission Sponsor and Application Correspondent

A. Submission Sponsor

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B. Application Correspondent

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Phone: +49-721-476-4847
Fax: +49-721-476-4849
Contact: Mr. Arne Briest

2. Date Prepared

Date Prepared: August 2, 2016

3. Device Identification

Trade/Proprietary Name:	Fehling Punches CERAMO® CONCEPT X CERAMO® CONCEPT CLASSIC CERAMO® CONCEPT APART CERAMO® GENTLE CERAMO® GENTLE "SINGER" CERAMO® TRADITION X CERAMO® FIST CERAMO® EJECTOR CERAMO® SUBLAMINAR CERAMO® APART CERAMO® KERRISION
Common/Usual Name:	Rongeur, Manual
Classification Name:	Manual Rongeur
Classification Regulation	21 CFR 882.4840
Product Code:	HAE
Device Class:	Class II
Classification Panel	Neurology

4. Legally Marketed Predicate Device

K150428 – Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs, cleared April 16, 2015

K092227 – Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs, cleared February 17, 2010

5. Device Description

Fehling-Punches are reusable stainless steel instruments that are coated with CERAMO® that are sterilizable and packaged non-sterile.

The instruments are offered in various sizes and with different features to accommodate the variations of patient anatomy and access. Instruments are available with the following features: 0.8-8 mm bite sizes; 9 – 19 mm jaw openings; 40° and 90° up/down cutting angles; up/down curved; regular and thin profile footplates; standard and ejector tips; 110 – 400 mm shaft lengths; and various handle and shaft styles, detachable and non-detachable. Fehling-Punches are distributed under the following brand names: CERAMO® CONCEPT X, CERAMO® CONCEPT CLASSIC, CERAMO® CONCEPT APART, CERAMO® GENTLE, CERAMO® GENTLE "SINGER", CERAMO® TRADITION X, CERAMO® FIST, CERAMO® EJECTOR, CERAMO® SUBLAMINAR, CERAMO® APART, CERAMO® KERRISION

The instruments are made of stainless steel according to ASTM F899 and are coated with CERAMO®. CERAMO® is an AlTiN coating.

A reusable screwdriver (item code TXW-9X) is offered with the Fehling Punches for the assembly and disassembly.

6. Indications for Use

Fehling rongeurs (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

7. Substantial Equivalence Discussion

	new device	**Predicate Integra (Kerrison Rongeurs)**	**Predicate Integra (Kerrison Rongeurs)**
510(k)	K153243	K150428	K092227
Product Code	HAE	HAE	HAE
Class	II	II	II
Regulation #	882.4840	882.4840	882.4840
Classification Name	Manual, Rongeur	Manual, Rongeur	Manual, Rongeur
Indication for use	FEHLING rongeurs (bone punches) are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	Integra Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	Integra Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.
Sterility	Non Sterile	Non Sterile	Non Sterile
Cleaning	Instrument can be processed in a validated washer-disinfector prior sterilization	Instrument can be processed in a validated washer-disinfector prior sterilization	Instrument can be processed in a validated washer-disinfector prior sterilization
Material	420 and 304 Stainless Steels (ASTM F-899); Surface coatings: CERAMO® (TiAlN); Silicone	420 Stainless steel Surface coatings: Titanium Nitride(TiN); Diamond Coat and Hard-Coat™ (TiAlN); Stealth Coat and Smooth-Coat™ (Dicronite DL-5); Ultra-Coat™ (ZrN); PTFE (polytetrafluoroethylene [Teflon®]); Silicone (Elastosil® LR3003/80 A,B)	medical grade stainless steel (ASTM F-899)
Design Features	Manual, non-electrical, non-sterile, reusable, non-malleable	Manual, non-electrical, non-sterile, reusable, non-malleable	Manual, non-electrical, non-sterile, reusable, non-malleable

	new device	**Predicate Integra (Kerrison Rongeurs)**	**Predicate Integra (Kerrison Rongeurs)**
Design	Rongeur with a fixed and a sliding shaft and angled footplate Rongeur with one fixed shaft, one sliding shaft and a mouthpart	Rongeur with a fixed and a sliding shaft and angled footplate Rongeur with one fixed shaft, one sliding shaft and a mouthpart	Rongeur with a fixed and a sliding shaft and angled footplate Rongeur with one fixed shaft, one sliding shaft and a mouthpart
Tip	Scoop-shaped tip, various angles and sizes (see below)	Scoop-shaped tip, various angles and sizes (see below)	Scoop-shaped tip, various angles and sizes
Shaft length	110 – 400 mm	4.75 – 15" (approximately 121 mm – 381 mm)	4.75 – 15" (approximately 121 mm – 381 mm)
Jaw opening	9 – 19 mm	9 – 15,5 mm	9 – 15,5 mm
Bit Size	0.8 – 8 mm	1 – 6 mm	1 – 6 mm
Cutting angulation	40° and 90° up/down	40° and 90° up/down	40° and 90° up/down

The Fehling Punches have the same intended use, similar performance characteristics, are manufactured from similar materials and are similar in design to the predicate devices.

8. Non-Clinical Performance Data

Biocompatibility

Biocompatibility testing on the Fehling-Punches was conducted and evaluated per ISO 10993.

Cytotoxicity
The full strength EMEM10 test article showed no cytotoxic potential to L-929 mouse fibroblast cells.

Sensitization

The topical application of the 0.9% NaCl extract did not induce delayed sensitization in the guinea pig. The topical application of the sesame oil extract did not induce delayed sensitization in the guinea pig. Based on these test results, according to the ISO 10993-10 standard, the test article was not considered a sensitizer in the guinea pig maximization model.

Hemolysis
The mean hemolytic index for the test article by direct contact was of 1.40%, and the mean hemolytic index for the test article extracted was of 1.95%. The direct contact of the test article was non hemolytic and the test article extract was non hemolytic. The negative and positive controls performed as anticipated.

Acute Systemic Toxicity Study in Mice

There was no evidence of significant systemic toxicity or mortality after test article extracts injection. Each test article extracted met the requirements of the ISO 10993-11 standard.

Intracutaneous Study in Rabbits

The 0.9 % NaCL and sesame oil extracts of the test article met the requirements of the Intracutaneous injection test in rabbit according to the procedures described in the ISO 10993-10 standard.

All testing passed.

Performance Testing

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

Dynamic

The dynamic test was conducted to evaluate the fatigue resistance of the bone punches following 12.500 cutting simulations. The testing confirmed the integrity of both the predicate device and the Fehling-Punches.

Static

Performance testing was conducted to evaluate the cutting displacement in relation to the manual force applied for both the subject and predicate device. Testing confirmed that the mean force required to operate the subject device is comparable to that of the predicate device.

Engineering Analysis

- An engineering analysis of the Fehling-Punches and the Integra Kerrison Rongeurs was conducted to compare the design principles, dimensional characteristics, materials and mode of operation. Analysis showed that the subject and predicate devices are substantially equivalent in all of these parameters.

Cleaning – and Sterilization Validation

Fehling Instruments has successfully performed an automated cleaning validation according TIR 30 Technical report and a sterilization validation according to ISO 17665 Standards and AAMI TIR 12 Technical report- Full cycle 132°C and 4 minutes.

Test	Test Method	Results
Automated Cleaning validation	Automated Cleaning Effectiveness Study of the CERAMO Bone Punch according to AAMI TIR 30 technical report	Automated cleaning was validated
Sterilization validation	Validation of the Steam Sterilization in a Pre-Vacuum Air Removal Autoclave according to the ISO 17665 Standards and AAMI TIR 30 technical report – Full cycle 132°C and 4 min	Sterilization process was validated
Cytotoxicity test	ISO MTS cytotoxicity test	Non-cytotoxic
Irritation test	ISO Intracutaneous Study in Rabbits – Two Extracts	Non-irritant
Toxicity test	ISO Acute Systemic Toxicity Study in Mice – Two Extracts	Non-toxic
Hemolysis test	ISO 10993 and ASTM Hemolysis	Non- hemolytic
Pyrogenity test	USP – Rabbit Pyrogen Study according to United States Pharmacopeia 38 – National Formulary 33 (USP)	Non-pyrogenic for devices that have undergone validated cleaning and sterilization.
Sensitization test	ISO Guinea Pig Maximization Sensitization Test – Two Extracts	Non- sensitizer
LAL-Test	Bacterial endotoxin quantification - LAL chromogenic method according to the European and American Pharmacopeia	Non-pyrogenic for devices that have undergone validated cleaning and sterilization.
Coating thickness verification	Determination of coating thickness on bone punches with an electron microscope	It was verified that the coating thickness of FEHLING bone punches is present on all relevant surface areas of the device and the layer lies in a range that ensures that all advantages of the coating are given.
Dimensional Verification	Dimensional Verification Test according to the actual specifications of the bone punches	The dimensional and functional specifications of the devices were verified.
Performance testing	Performance Tests according to defined parameters describing worst case of use and extended use.	The devices passed the tests. One deviation occurs, but was probably due to misplacement of the probe

9. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the Fehling Punches and the predicate devices do not raise any questions regarding safety and effectiveness.

Performance testing and compliance with voluntary standards, demonstrate that the Fehling Punches are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

The Fehling Punches are determined to be substantially equivalent to the referenced predicate devices.