DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 16, 2015

Integra York PA, Inc.
Ms. Stephanie Sheesley
Senior Manager, Regulatory Affairs
589 Davies Drive
York, Pennsylvania 17402

Re: K150428
Trade/Device Name: Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: February 18, 2015
Received: February 19, 2015

Dear Ms. Sheesley,

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

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)*
K150428

Device Name
Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs

Indications for Use *(Describe)*
Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs 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) Summary

I. SUBMITTER

Integra York PA, Inc.
589 Davies Drive
York, PA 17402 USA

Phone: (717) 717-840-3522
Fax: (717) 840-9347

Contact Person: Stephanie Sheesley
Date Prepared: April 15, 2015

II. DEVICE

Name of Device: Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs
Common Name: Kerrison Rongeur
Classification Name: Manual, Rongeur (21 CFR 882.4840)
Regulatory Class: Class II
Product Code: HAE

III. PREDICATE DEVICE

Integra® *Jarit®, Ruggles™ -Redmond™, Miltex®, and MeisterHand®* Kerrison Rongeurs, K092227

This predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

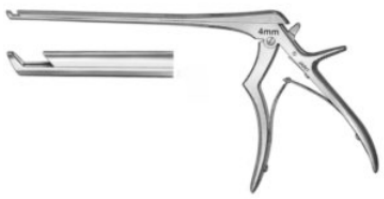
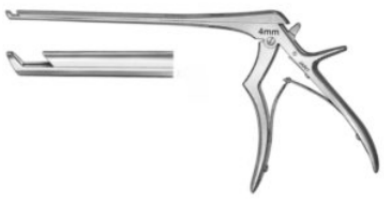
Integra® Kerrison Rongeurs are reusable stainless steel instruments that are sterilizable and packaged non-sterile. Devices are available with the following features: with or without proprietary surface treatments; 1-6 mm bite sizes; 9 - 15.5 mm jaw openings; 40° and 90° up/down cutting angles; regular and thin/low profile footplates; standard and ejector tips; 4.75 – 15" shaft lengths; and various handle and shaft styles, including Detach®. Integra® Kerrison Rongeurs are distributed under the following brand names: *Jarit®, Ruggles™ -Redmond™, Miltex®, and MeisterHand®*.

V. INDICATIONS FOR USE

Integra® (Jarit®, Ruggles™-Redmond™, Miltex®, MeisterHand®) Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

VI. COMPARISON OF TECHNOLOGICAL CHRACTERISTICS WITH THE PREDICATE DEVICE

The below table provides a comparison of the subject devices and the predicate devices.

	Integra York PA, Inc. Integra® Kerrison Rongeurs	Integra Medical Instrument Group (now Integra York PA, Inc.) Integra® Kerrison Rongeurs
510(k) #	Subject of Submission	K092227
Class	II	II
Pro Code	HAE	HAE
Regulation #	882.4840	882.4840
Classification	Manual, Rongeur	Manual, Rongeur
Indications for Use	Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.	Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.
Contact Materials	420 Stainless steel Surface coatings: Titanium Nitride(TiN); Diamond Coat and Hard-Coat™ (TiAIN); Stealth Coat and Smooth-Coat™ (Dicronite DL-5); Ultra-Coat™ (ZrN); PTFE (polytetrafluoroethylene [Teflon®]); Silicone (Elastosil® LR3003/80 A,B)	420 Stainless steel Surface coatings: Titanium Nitride(TiN); Diamond Coat and Hard-Coat™ (TiAIN); Stealth Coat and Smooth-Coat™ (Dicronite DL-5); Ultra-Coat™ (ZrN); PTFE (polytetrafluoroethylene [Teflon®]); Silicone (Elastosil® LR3003/80 A,B)
Instructions for Use	Sterilize in either the Assembled or Disassembled, Open Position. Successful Sterilization Validation supports Assembled and Open Configuration	Sterilize in Disassembled, Open Position.
Technological Characteristics	Identical to Predicate	Manual, non-electrical, non-sterile, reusable
Malleability	Non-malleable	Non-malleable
Sterility	Non-sterile	Non-sterile
Sterilization	Sterilizable	Sterilizable
Utility	Reusable	Reusable
Energy Source	N/A (manual)	N/A (manual)
Image of Example Kerrison Rongeur – Detach Shaft		

There are no differences in technology, materials, intended use, or design between the subject devices and the above predicates. The only change is with respect to the labeling. The Instructions For Use for the predicate device stated that the device was to be sterilized in the disassembled but open configuration. The Instructions for Use for the subject devices allows the devices to be sterilized in the either the disassembled or assembled, but open configuration. This change is supported by a successful sterilization validation.

VII. PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. No new testing was required to be performed in support of this labeling change. This Special 510(k) pre-market notification includes the sterilization validation submitted with the predicate device submission #K092227 as a reference only.

The below testing is provided as a reference to support the labeling change subject to this Special 510(k). This testing is not new and was previously included in the 510(k) submission #K092227 and was deemed acceptable to support the proposed labeling change per Pre-Submission #Q141112.

Testing Performed	**Results**
Pre-Vacuum (wrapped) Steam Sterilization Validation per ANSI/AAMI ST79:2010 & A1:2010 and ANSI/AAMI/ISO 14937:2009 at 270°F (132°C) with an Exposure Time of 4 minutes and Drying Time of 20 minutes	**Pass**

No biocompatibility testing was performed as a result of this Special 510(k) as the subject devices are not under-going a change in materials – this submission is for a labeling change only.

VIII. CONCLUSIONS

The labeling was the only change submitted under this Special 510(k) and supports the substantial equivalence to the predicate device.