510(k) Summary

APR 1 1 2014

Submitted by:	Integra York PA, Inc. 589 Davies Drive York, PA 17402 USA
Contact Person:	Ruthanne Vendy Regulatory Affairs Manager Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA Phone: (717) 757-7974
Date Prepared:	January 31, 2014
Device Trade Name:	Integra® Gynecological Forceps
Brands:	Jarit®, Miltex®, and MeisterHand®
Device Common Name(s):	Gynecological Forceps; Vulsellum Forceps; Uterine Vulsellum Forceps; Tumor Forceps; Uterine Elevating Forceps; Hysterectomy Forceps; Uterine Artery Forceps; Membrane Puncturing Forceps; Placenta Forceps; Uterine Polyps Forceps; Forceps; Clamp
Classification Name:	Forceps, Surgical, Gynecological
Device Class:	Class II
Product Code:	HCZ
CFR Classification:	21 CFR 884.4530

Device Description:
Integra® Gynecological Surgical Forceps are designed to provide a secure grip on tissue during vaginal and abdominal hysterectomy procedures. These atraumatic instruments are designed to minimize laceration or perforation of the tissue even when required retraction is exerted. Due to differences in anatomy of the site and types of surgical procedures, a variety of configurations and models are offered to provide the surgeon with options to ensure clinical needs are met.

Indications For Use:
Integra® Gynecological Surgical Forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological procedures.

Predicate Devices:

	Device	Manufacturer
Preamendment	Miltex® Gynecological Forceps	E. Miltenberg, Inc.
K092840	Forceps Obstetrical/Gynaecological	Instrumed International, Inc.
Preamendment	Miniclamps, Stabiliz, Fallopian Tube	Sklar Corporation

Technological Comparison of Subject Devices to Predicates:

	Integra York PA, Inc. Gynecological Forceps	E. Miltenberg, Inc. (now Integra York PA, Inc.) Gynecological Forceps	Instrumed International, Inc. OB/GYN Forceps	Sklar Corporation Gynecological Forceps
510(k) #	Subject of Submission	Preamendment	K092840	Preamendment
Class	II	II	II	II
Pro Code	HCZ	HCZ	HCZ	HCZ
Regulation #	884.4530	884.4530	884.4530	884.4530
Classification	Obstetric-gynecologic manual instrument	Obstetric-gynecologic manual instrument	Obstetric-gynecologic manual instrument	Obstetric-gynecologic manual instrument
Intended Use	used to pull, grasp, or compress during gynecological examination	used to pull, grasp, or compress during gynecological examination	used to pull, grasp, or compress during gynecological examination	used to pull, grasp, or compress during gynecological examination
Patient Contact Materials	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Malleability	Non-malleable	Non-malleable	Non-malleable	Non-malleable
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Sterilization	Sterilizable	Sterilizable	Sterilizable	Sterilizable
Utility	Reusable	Reusable	Reusable	Reusable
Energy Source	N/A (manual)	N/A (manual)	N/A (manual)	N/A (manual)
Device Sizes	Varied	Varied	Varied	Varied
Components	1-piece	1-piece	1-piece	1-piece
Substantially Equivalent	N/A	Yes[1]	Yes[1]	Yes[1]

[1] Evaluative Statement: These devices are completely comparable to the predicate instruments. There are no significant differences in technology, intended use, or design between the subject devices and the predicates selected. The minor differences between patterns have no impact on equivalence.

Performance Standards:

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the following standards were used to assess the Integra® Gynecological Forceps:

- AAMI TIR12:2010 – *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
- AAMI TIR30:2011 – *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

- ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012 – *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- ASTM F 899-11 – *Standard Specification for Wrought Stainless Steels for Surgical Instruments*
- ASTM F 1089-02 – *Standard Test Method for Corrosion of Surgical Instruments*
- ISO 13402:1995 – *Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure*
- ISO 7153-1:2001 – *Surgical instruments -- Metallic materials -- Part 1: Stainless steel*

Non-Clinical Testing Performed	Results
Manual Cleaning Validation	**Pass**
Automated Cleaning Validation	**Pass**
Pre-Vacuum Steam Sterilization Validation at 270°F (132°C) for 4 minutes	**Pass**
Gravity Displacement Steam Sterilization Validation at 270°F (132°C) for 15 minutes	**Pass**
Corrosion Testing	**Pass**

No biocompatibility testing was performed on the proposed devices, as stainless steel AISI 420 is recognized as a suitable stainless steel for surgical instruments per ASTM F899-11 and ISO 7153-1. AISI 420 has a long history of safe and effective use, and has been used in other medical devices that have been cleared by the FDA (e.g., K971977).

Conclusions drawn from Non-Clinical Data:
All necessary testing has been performed on the Integra® Gynecological Forceps and the results support the conclusion that the subject devices are substantially equivalent to the legally marketed predicate devices based on intended use, materials, technology, and design and as such, do not raise any concerns of safety or effectiveness.

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 11, 2014

Integra LifeSciences Corporation
Integra York PA, Inc.
Ruthanne Vendy, RAC
Regulatory Affairs Manager
589 Davies Drive
York, PA 17402

Re: K134047
Trade/Device Name: Integra® Gynecological Forceps
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HCZ
Dated: January 28, 2014
Received: February 3, 2014

Dear Ruthanne Vendy,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K134047

Device Name: Integra® Gynecological Forceps

Indications for Use:

Integra® Gynecological Surgical Forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter-Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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