K120012

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510(k) Summary

SEP 11 2012

Submitted by:	Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA
Contact Person:	Stephanie Sheesley, Sr. Regulatory Affairs Manager Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA Phone: (717) 717-840-2774 Fax: (717) 840-9347
Date Prepared:	December 22, 2011
Device Trade Name:	Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments
Device Common Name:	Minimally Invasive Surgical Instruments
Classification Name:	Endoscope and accessories
Device Class:	Class II
Product Code:	GCJ
CFR Classification:	21 CFR 876.1500

Device Description:
Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are a family of manual, stainless steel instruments consisting of clamps, forceps, needle holders, scissors, knot tiers/pushers, and suction instruments. These reusable devices are packaged non-sterile and are steam sterilizable.

Indications For Use:
Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are manually operated instruments designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, draining, aspirating, suturing or ligating during open, mini-open, or thoracoscopic surgical procedures.

INTEGRA
LIMIT UNCERTAINTY

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Predicate Devices:

510(k) #	Device	Product Code	Manufacturer
K945474	Scanlan® Thoracoscopic Scissors, Clamps, Forceps, Needle Holder	GCJ	Scanlan Intl, Inc.
K925198	Kaiser "No Cannula" Thoracoscopic/ Laparoscopic Instruments	GCJ	Pilling Co.
K932456	Jarit Surgical Instruments	KNF	Integra York PA, Inc.
K941565	Jarit Recommended Sinus Instruments	EOB	Integra York PA, Inc.

Performance Standards:

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Integra™ Jarit® Video Assisted Thoracic Surgery Instruments conform to the following standards:

- ANSI/AAMI ST79:2010 & A1:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI/ISO 14937:2009 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process
- ASTM TIR 30:2003 A Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- 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
- ASTM F899-11 Standard Specification for Wrought Stainless Steels for Surgical Instruments

Performance Data:

Testing Performed	Results
Manual Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
Mechanical Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
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.	**Pass**
Repeated Autoclave Testing, Boiling Water Testing, Copper Sulfate Corrosion Testing and Thermal Testing per ISO 13402 and ASTM F 1089-02.	**Pass**

Substantial Equivalence:

Integra™ Jarit® Video Assisted Thoracic Surgery Instruments are substantially equivalent to the legally marketed predicate devices based on intended use, materials, and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Integra LifeSciences Corporation
% Integra York PA, Incorporated
Ms. Stephanie Sheesley
Senior Regulatory Affairs Manager
589 Davis Drive
York, Pennsylvania 17402

SEP 11 2012

Re: K120012
Trade/Device Name: Integra™ Jarit® Video Assisted Thoracic Surgery
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 8, 2012
Received: August 10, 2012

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 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,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K 120012

Device Name: Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments

Indications for Use:

Integra™ Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are manually operated instruments designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, draining, aspirating, suturing or ligating during open, mini-open, or thoracoscopic surgical 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120012