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

January 22, 2016

Sontec Instruments Inc.
% Mr. Charles Hart
Principle Consultant
Hart Consulting LLC
2964 Redhaven Way
Littleton, Colorado 80126

Re: K152400
Trade/Device Name: General & Plastic Surgery Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 21, 2015
Received: December 21, 2015

Dear Mr. Hart:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K152400

Device Name
General & Plastic Surgery Instruments

Indications for Use *(Describe)*
Manually operated minimally invasive General & Plastic Surgery Instruments designed to perform specific functions such as aspirating, clamping, cutting, dissecting, draining, grasping, ligating, probing, or suturing during open, mini-open, or endoscopic surgical procedures such as thoracoscopy and laparoscopy.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| | | | |
|---|---|---|---|
| Date prepared: | September 17, 2015 | | |
| Applicant: | Sontec Instruments Inc. | | |
| Contact person: | Stefan M. Scanlan<br>Vice President<br>7248 South Tucson Way<br>Centennial, Colorado 80112<br>Phone: (303) 790-9411<br>Fax: (303) 792-2606<br>Email: sscanlan@sontecinstruments.com | | |
| Trade names: | General & Plastic Surgery Instruments | | |
| Common name: | Minimally Invasive Surgical Instruments (Endoscope & Accessories) | Class: | II |
| Classification name: | Endoscope & Accessories | Product code: | GCJ |
| Predicate device: | K120012; K110121; K945474; K925198 | | |

Device description:

Sontec Instruments are a family of manual, instruments consisting of Clamps, Forceps, Knot Tiers, Needle Holders, Knot Pushers, Scissors and Suction Tips. These reusable devices are packaged non-sterile and are steam sterilizable.

Indications for Use:
Sontec Instruments are manually operated instruments designed to perform specific functions such as aspirating, clamping, cutting, dissecting, draining, grasping, ligating, probing, or suturing during open, mini-open, or endoscopic surgical procedures such as thoracoscopy and laparoscopy.

Technological characteristics:
All components of the Clamps, Forceps, Knot Tiers, Needle Holders, Knot Pushers, Scissors and Suction Tips are comprised of materials which are in accordance with ISO 10993-1:2009. The contact time (<24 Hrs.) and type of contact (External Communicating Devices: Tissue, Bone, Dentin).

| Material | Material Designation | | Chemical compositions MAX (mass/mass %) |
|---|---|---|---|
| Stainless Steel (e.g.17-4/304/420) | ISO 7153-1/ ASTM F899 | ISO 15510/ ASTM A276/ ASTM A564/ ASTM A484 | C .08, Mn 2.0, Si 1.0, S .03 P.045, Cr 15-20, Ni 3-11, Cu 3-5 |
| Titanium | ISO 5432/ASTMF136/ASTMB265 | | N .05 C .08 H .012 Fe .25 O .13 Al 5.5-6.5 Va 3.5-4.5 Ti Balance |
| Aluminum 5052 | MIL 8625 | | Si .25, Fe .4, Cu, .1, Mn .1, Mg 2.2-2.8, Cr .15-.35, Z .1, Other .15, Al remainder |
| Tungsten Carbide G4 | N/A | | TC 87%, Co12%, TA/NbC 1% |

Cleaning Metallic Medical Instruments is conducted per ASTM A380 post manufacturing to ensure that materials are free from machining oils.

The products will be provided clean, non-sterile, and intended to be reused and the cleaning and sterilization validations were carried out in accordance with ASTM F1744 and ANSI/AAMI ST79.

The packaged device will withstand normal shipping and storage environments and labeling shall meet 21CFR 801, EN 1041, and ISO 15223.

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|---|---|
| Non-clinical tests submitted or relied upon: | Cleaning, Thermal Disinfection and Steam Sterilization Validations of Subject Reusable Hand Held Surgical Instruments |
| Clinical tests submitted or relied upon: | None |
| Substantial equivalence conclusion: | The Sontec General & Plastic Surgery Instruments are substantially equivalent to the legally marketed FDA cleared predicate devices, based on intended use, design, material, chemical composition, and energy source. The proposed devices do not introduce new issues of safety or effectiveness. |