Page 1 of (3)

510(K) SUMMARY

SIALOTECH MODULAR ENDOSCOPE

510(k) Number K093785

AUG 18 2010

Applicant Name:

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Date Prepared: June 2010

Trade Name: Modular Endoscope

Classification Name: CFR Classification section 876.1500 (Product code GCJ)

Classification: Class II medical Device

Predicate Device:

The Modular Endoscope is comparable to the following predicate devices:

- KSEA Sialoendoscope and accessories (K012527) manufactured by Karl Storz Endoscopy.
- Midiview series of microendoscopes (K051073) manufactured by Millennium Devices Inc.
- SpyGlass™ Direct Visualization Probe (K050403) manufactured by Boston Scientific Corporation.
- OraScope (K991101) manufactured by FiberDent Corp.

K093785

Device Description:

The Modular Endoscope utilizes a fiberoptic technology to allow visualization of body cavities. The 6000/10,000 pixel optic system is semi rigid and is contained within a very small diameter of less than 1mm. The endoscope contains a working channel to allow access of various accessories for different therapeutic applications.

The Modular Endoscope is used with single use, multi port (2 or 3 port), sterile cannulas with diameters ranging from 0.9-2.3 mm, which provide the surgeon good flexibility in choosing the right equipment for the clinical procedure.

The single lumen cannula is inserted into the salivary gland or other body cavities or canals and serves as a working and irrigation channel, as well as containing the fiberoptic system. The fiberoptic system is protected from surgical tools and instruments by a nitinol coating.

An ocular is connected at the proximal end and light is transmitted via a light source cable from various commercially available Xenon lamp light sources to the optic system. The image can be visualized by connecting the endoscope to a camera and a monitor screen. The light source, camera and monitor are user-supplied.

Intended Use/Indication for Use:

The Modular Endoscope is intended for use for visualization and to magnify and illuminate body cavities, hollow organs and canals in ENT procedures. The Modular Endoscope is intended for use for visualization and to magnify and illuminate dental surfaces. The Modular Endoscope is intended for using additional accessories to perform various diagnostic and therapeutic procedures in ENT surgery, including but not limited to, salivary gland diseases.

Performance Standards:

The Modular Endoscope has been tested and complies with the following voluntary recognized standards:

- *Electrical & Mechanical Safety testing according to IEC 60601-1 & IEC 60601-2-18*
- Electromagnetic Compatibility testing according to IEC 60601-1-2
- Optic system testing according to ISO 8600 Parts 1, 3, 4, and 5
- AAMI TIR30:2003 "A *compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
- ISO 11135-1:2007 *"Sterilization of health care products- Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"*
- ISO 10993-7:2008 *"Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals".*

- ISO 14937:2000 *"Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.*
- AAMI TIR12:2004 - *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.*
- ANSI/AAMI/ISO 17665-1:2006 *Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices.*
- ANSI/AAMI ST79:2006 - *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
- AAMI/ANSI ST77:2006 - *Containment devices for reusable medical device sterilization.*

Non-Clinical Performance Data:

The Modular Endoscope has been tested for performance as follows:

- Resolution and Distortion testing

Clinical Performance Data:

Although clinical data is not required to support the substantial equivalence of the Sialo Modular Endoscope, information regarding the use of the device for dental surfaces is presented in Section 20.

Substantial Equivalence:

The Modular Endoscope is similar in its intended use, indications for use, operation, performance and technological characteristics to currently marketed endoscopes intended for diagnosis and treatment of salivary gland diseases and root canal treatment, such as the Karl Storz KSEA Sialoendoscope (K012527), the OraScope manufactured by FiberDent Corporation (K991011), the Midiview series of microendoscopes (K051073) manufactured by Millennium Devices Inc., and the SpyGlass™ Direct Visualization Probe manufactured by Boston Scientific Corporation (K050403). The minor differences in the Modular Endoscope compared to the predicate devices do not raise new issues of safety or effectiveness.

Conclusions:

Based on the performance testing and comparison to predicate devices, the Modular Endoscope is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Ms. Ahava Stein
20 Hata'as Street, Suite 102
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AUG 18 2010

Re: K093785
Trade/Device Name: Modular Endoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 11, 2010
Received: August 11, 2010

Dear Ms. Stein:

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,

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

Enclosure

K093785

INDICATIONS FOR USE

510(k) Number (if known): K093785

Device Name: Modular Endoscope

Intended Use Statement:

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Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format 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 K093785