AUG 2 1 2012

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510(k) Summary

510(k) Summary as required by section 807.92 08/17/2012

>>Submission Applicant:
From: Endoservice Optical Instruments GmbH
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78576 Emmingen/Germany
Establishment Registration Number: 3009110146
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E-mail: info@endorep.com

>>Application Correspondent/Contact:
think!
Andrea Pecsi
Schwarzwaldstraße 5
78532 Tuttlingen
Germany
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E-mail: andrea@thinkworks.biz

>> Device Identification:

Trade name: **Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices**

Common name: Endoscopes

Classification name: Endoscope and accessories, Review Panel Gastroenterology/Urology (21 CFR 876.1500, FBP)
Subsequent Codes: FAJ, FBK, FDC, FED, FGC, FJL, EZO, LQR, KQT

>> Predicate Device Information:

510(k)-Number: K012660, GIMMI ALPHA® Instruments & Accessories
Firm: GIMMI GMBH

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>>Description of the Device:

Endoservice Endoscopic Instruments & Accessories are comprised of rigid, panoramic telescopes using rod lens technology. The body contact portions are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility.

The urological-gastroenterological accessories are composed of reusable handle and shaft assemblies and removable, reusable tip assemblies. The instruments are designed and manufactured specifically for the purpose of manipulating soft tissue, body cavities, hollow organs and canals (grasping, cutting, dissecting, coagulating and suturing).

The Endoservice Endoscopic Instruments & Accessories and Minimally Invasive gastrointestinal GI and genitourinary GU Devices contain different components such as Scissors, Forceps, Connections (inner Rod, Sheath insulated), Handles, Sheaths, Endoscopes, Cystoscopes, Resectoscopes, Urethrotomy, Retractor, Forceps, Scissors, Punches, Tubes, Trocars, Trocar Sleeves, Sheat, Needle holder, and Inserts.

The device is made out of following materials:
Body: steel 1.4301; plastic PPSU
Handle: adhesive hysol-resin
Lens: saphir

>>Indications for Use:

Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices are intended to be used by qualified physicians to provide access and visualization of internal structures such as bladder, urethra, kidneys, prostate and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing).

>> Technological characteristics compared to the Predicate Device:

The Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices are identical to the predicate device GIMMI ALPHA® Instruments in terms of design, technical characteristics, intended use, indications for use, sterilization processes. In terms of components the predicate device has a comparable product range included in the submission as the new device. The Endoservice devices are belonging to the Urology and Gastroenterology Panel. Furthermore the used materials stainless steel and insulation material are also similar in both products.
For more details see table below.

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	Endoservice Endoscopic Instruments New device	GIMMI ALPHA® Instruments K012660
Diameter Lengths	>>*Tube* 3,5-12,5mm Tube, various from 70cm to 150cm >> *Cystoscope, Resectoscope, Urethrotome* Length: 298-310mm Diameter: 2.7mm, 2.8mm, 2.9mm, 4.0mm	>>*Tube* 3,5-12,5mm Tube, various from 40 cm to 105 cm >> *Laparoscope* Length: 270mm-330mm Diameter: 5.0mm, 10mm,11mm >> *Cystoscope, Resectoscope, Urethrotome* Length: 300mm Diameter: 4.0mm
Material	Stainless Steel1.4301; plastic PPSU adhesive hysol-resin saphir lens	Stainless Steel Insulation material
Components	Scissors, Forceps, Connections (inner Rod, Sheath insulated), Handles, Sheaths, Endoscopes, Cystoscopes, Resectoscopes, Urethrotomy, Retractor, Forceps, Scissors, Punches, Tube, Sheat, Needle holder, and Inserts.	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Knife, Hook, Knot Guide, Retractors, Divers and Blades

>> Non-clinical performance data:

On the Endoservice Endoscopic devices were performed Bending Tests, Material Tests, Bench Tests, Validation Tests of Sterilization, Disinfection and Cleaning (automatically), Cytotoxicity Test, and Microbiological Test for determination of microorganisms.

>>Summary:

The product components which are covered by this 510(k) premarket notification have been successfully tested among others according to ISO 8600, ISO 10993, ISO 11737, ISO 17665, ISO 15883, and ISO 14971. The conclusions drawn from the nonclinical test performed on the Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices show in its results that the devices are as safe and as effective, and perform as well as or better than the legally marketed device, therefore do not raise new issues regarding safety and effectiveness.

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

Endoservice Optical Instruments GmbH
% Ms. Andrea Pécsi
Regulatory Affairs Specialist
think!
Schwarzwaldstraße 5
TUTTLINGEN 78532
GERMANY

AUG 2 1 2012

Re: K113062
Trade/Device Name: Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBP
Dated: July 31, 2012
Received: August 2, 2012

Dear Ms. Pécsi:

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.

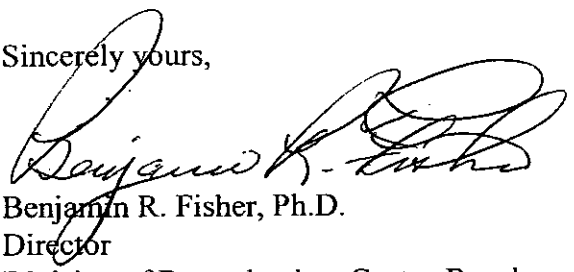
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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 Statement

510(k) Number (if known): K113062

Device Name: **Endoservice Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices**

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113062