K073164
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510(k) Summary of Safety and Effectiveness

MAR - 5 2008

SUBMITTER:	Covidien UK Manufacturing Ltd. 20 Garryduff Road, Ballymoney County Antrim, Ireland BT53 7AP Phone: 44 28 2766 3234
CONTACT PERSON:	Sharon Alexander Senior Associate, Regulatory Affairs Covidien 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-6060
DATE PREPARED:	March 4, 2008
TRADE/PROPRIETARY NAME:	IVS Tunneller™ Device
COMMON/USUAL NAME:	Intra-Vaginal Sling Placement Device
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	IVS Tunneller™ Intra-Vaginal Sling (K010035) Parietene® Polypropylene Mesh (K991400) Surgipro™ Polypropylene Surgical Mesh (K915526)
DEVICE DESCRIPTION:	The IVS Tunneller™ Intra-Vaginal Sling placement device is comprised of three components: a stainless steel introducer or outer sheath, a polypropylene stylette, and a polypropylene mesh tape. The introducer is a curved stainless steel tube with a delta wing polypropylene handle, which is used to create a pathway for the correct placement of the polypropylene mesh tape. The polypropylene stylette has an eyelet for threading the polypropylene mesh tape and an atraumatic conical tip which allows for blunt tissue dissection and muscle deflection during the passage of the introducer. The polypropylene mesh tape is a non-absorbable, inert, porous, surgical mesh tape, created from either monofilament or multifilament yarns, and is supplied sterile.
INTENDED USE:	The IVS Tunneller™ Intra-Vaginal Sling placement device is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.
TECHNOLOGICAL CHARACTERISTICS:	The fundamental scientific technology of the IVS Tunneller™ Intra-Vaginal Sling placement device is substantially equivalent to the predicate IVS Tunneller™ device.
MATERIALS:	All components of the IVS Tunneller™ Intra-Vaginal Sling placement device have been evaluated in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	The performance of the subject IVS Tunneller™ device is substantially equivalent to the currently marketed predicate IVS Tunneller™ device.

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510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien UK Manufacturing Ltd. 20 Garryduff Road, Ballymoney County Antrim, Ireland BT53 7AP Phone: 44 28 2766 3234
CONTACT PERSON:	Sharon Alexander Senior Associate, Regulatory Affairs Covidien 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-6060
DATE PREPARED:	March 4, 2008
TRADE/PROPRIETARY NAME:	Obturator IVS Tunneller™ Device
COMMON/USUAL NAME:	Intra-Vaginal Sling Placement Device
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	IVS Tunneller™ Intra-Vaginal Sling (K010035) Parietene® Polypropylene Mesh (K991400) Surgipro™ Polypropylene Surgical Mesh (K915526)
DEVICE DESCRIPTION:	The Obturator IVS Tunneller™ Intra-Vaginal Sling placement device is comprised of three components: a stainless steel introducer or outer sheath, a polypropylene stylette, and a polypropylene mesh tape. The introducer is a curved stainless steel tube with a delta wing polypropylene handle, which is used to create a pathway for the correct placement of the polypropylene mesh tape. The polypropylene stylette has an eyelet for threading the polypropylene mesh tape and an atraumatic conical tip which allows for blunt tissue dissection and muscle deflection during the passage of the introducer. The polypropylene mesh tape is a non-absorbable, inert, porous, surgical mesh tape, created from either monofilament or multifilament yarns, and is supplied sterile.
INTENDED USE:	The Obturator IVS Tunneller™ Intra-Vaginal Sling placement device is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI) and for mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.
TECHNOLOGICAL CHARACTERISTICS:	The fundamental scientific technology of the Obturator IVS Tunneller™ Intra-Vaginal Sling placement device is substantially equivalent to the predicate IVS Tunneller™ device.
MATERIALS:	All components of the Obturator IVS Tunneller™ Intra-Vaginal Sling placement device have been evaluated in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	The performance of the subject Obturator IVS Tunneller™ device is substantially equivalent to the currently marketed predicate IVS Tunneller™ device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2008

Covidien UK Manufacturing Ltd.
% Covidien
Ms. Sharon Alexander
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K073164
Trade/Device Name: Obturator IVS Tunneller™ Intra-Vaginal Sling Placement Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 21, 2008
Received: February 22, 2008

Dear Ms. Alexander:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K073164
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Indications For Use

510(k) Number (if known): K073164

Device Name: IVS Tunneller™ Intra-Vaginal Sling Placement Device

Indications For Use:

The IVS Tunneller™ Intra-Vaginal Sling placement device is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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)

Neil R P Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073164

K073164
(pg 2 of 2)

Indications For Use

510(k) Number (if known): K073164

Device Name: Obturator IVS Tunneller™ Intra-Vaginal Sling Placement Device

Indications For Use:

The Obturator IVS Tunneller™ Intra-Vaginal Sling placement device is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI) and for mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

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)

for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073164