DIMA		KIM (Knotless Incontinence Mesh)	K103022

510K Summary:

SUBMITTER:	Neomedic International, S.L. C/ Maestrat 41-43 1° 08225 Terrassa (Barcelona) Spain
US Contact Person:	Dr. Jeffrey R. Shideman Telephone: (952) 835-4018
DATE PREPARED:	December 15th , 2011
DEVICE NAME:	KIM (Knotless Incontinence Mesh)
CLASSIFICATION NAMES:	Mesh, Surgical, Polymeric
PREDICATE DEVICES:	K033568 Gynecare TVT Obturator System K081275 Boston Scientific Surgical Mesh K072456 Desara Mesh Sling Model CALD-DS01 K083471 GMD Universal Sling Model Product Code 1010 and 1020 K052175 I-Stop Mid-Urethral Sling

Device Description:

KIM (Knotless Incontinence Mesh) is a sterile, single use surgical mesh kit for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

KIM (Knotless Incontinence Mesh) is composed by a monofilament polypropylene mesh sling and two passers used to pass the sling through the obturator foramens.

Polypropylene monofilament traction threads are fixed at each end of the mesh to facilitate the attachment of the passers to the mesh.

The passers are used to deliver the sling via the trans-obturator "out-inside" approach.

The traction threads are removed after placement of the sling.

When placing the mesh, the sling can be adjusted by the surgeon to leave the mesh flat under the urethra, at the proper tension providing extra support to the urethra.

Description of material components and physical properties:

Component	Material
Monofilament polypropylene mesh	Polypropylene monofilament
Traction threads	Polypropylene monofilament
Transition cones	POM
Passers	Stainless steel AISI 303 POM

Component	Properties
Monofilament polypropylene mesh	Knitted mesh Monofilament diameter = 0.14 mm Tensile break strength = 180±20 Newton Pore size = 1.45±0.40 mm Thickness = 0.45±0.05 mm Density = 59.8 g/m2 Porosity = 52.00 %
Traction threads	USP 0
Transition cones	Diameter: 4 mm Length: 10 mm
Passers	Passers diameter = 4 mm

Predicate Devices:

The following four devices have been previously cleared by the FDA in the following 510(K)

Device	510 (K) document number	Date Cleared	Indications
GYNECARE TVT OBTURATOR SYSTEM	K033568	December 8 2003	Treatment of Stress Urinary Incontinence
BOSTON SCIENTIFIC SURGICAL MESH	K081275	August 27 2008	Treatment of Stress Urinary Incontinence
DESARA MESH SLING, MODEL CALD-DS01	K072456	May 8 2008	Treatment of Stress Urinary Incontinence
GMD UNIVERSAL SLING, MODEL PRODUCT CODE 1010 AND 1020	K083471	March 3 2009	Treatment of Stress Urinary Incontinence
I-STOP MID-URETHRAL SLING	K052175	October 17 2005	Treatment of Stress Urinary Incontinence

Intended Use:

KIM (Knotless Incontinence Mesh) is a surgical mesh kit for treatment of female stress urinary incontinence resulting from urethral hyper mobility and / or intrinsic sphincter deficiency.

Technological Characteristics comparison:

The KIM Surgical Mesh and the five predicate devices are substantially equivalent:

The five predicate devices are intended for the treatment of stress urinary incontinence.
The five predicate devices are monofilament polypropylene mesh slings.
The five predicate devices include accessories to aid in mesh placement.
The five predicate devices deliver the sling via the trans-obturator approach.
The five predicate devices are sterilized by ETO.
BOSTON SCIENTIFIC SURGICAL MESH and I-STOP MID-URETHRAL SLING are not covered by a plastic sheath.

There are differences compared to the predicate devices:

1.- GYNECARE TVT, DESARA MESH SLING and GMD UNIVERSAL SLING are covered by a plastic sheath.

The differences between the devices do not raise new questions on the safety and effectiveness. We consider the proposed device is substantially equivalent to the predicate devices.

Performance tests:

Performance test	Test description
Sterilization	Bioburden Ethylene oxide residuals Ethylene chlorohydrins residuals Sterility assurance level (SAL) determination
Packaging	Expiration dating test
Biocompatibility	Cytotoxicity Implantation Sensitization with polar and non-polar extract Genotoxicity Acute systemic toxicity Irritation Haemolysis Extractable metallic ions Pyrogen test
Mechanical tests	Suture pullout strength Tensile break strength at break Tear resistance Pore size Thickness Density Porosity Traction threads-mesh strength

Results of verification testing indicate that the product meets the established performance requirements and standards.

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the proposed device is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

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

Neomedic International S.L.
% Jeffrey R. Shideman, Ph.D.
President
International Medical Products Corporation
7307 Glouchester Drive
EDINA MN 55435

SEP 28 2012

Re: K103022
Trade/Device Name: KIM (Knotless Incontinence Mesh)
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: November 28, 2011
Received: December 1, 2011

Dear Dr. Shideman:

This letter corrects our substantially equivalent letter of December 20, 2011.

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 (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 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" (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 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

510(k) Number (if known): K103022

Device Name: KIM (Knotless Incontinence Mesh)

Indications for Use:

KIM (Knotless Incontinence Mesh) is a surgical mesh kit for treatment of female stress urinary incontinence resulting from urethral hyper mobility and / or intrinsic sphincter deficiency

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103022