K063079 1/1

510(k) Summary

NOV - 7 2006

- **Submitter's name:** CL Médical
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  Pre Center II
  F – 69110 Sainte Foy Les Lyon - FRANCE
- **Tel:** + 33.(0)4.78.59.54.93
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- **Contact person:** Mr. Vincent GORIA

- **Date of summary preparation:** October 2nd, 2006
- **Device common name:** Surgical mesh, Sling, Urethral Sling
- **Device trade name:** I-STOP® Trans Obturator Male / Female Sling
- **Device classification name:** Surgical mesh, polymeric (21 CFR 878.3300)

- **Product code:** FTL
- **Regulatory status:** Class II
- **Predicate Device:** I-STOP K051533
  AMS Male Transobturator Sling System K053371

- **Device description:**
  I-STOP® Trans Obturator Male / Female Sling is a sterile, single use kit consisting of one sling of knitted monofilament polypropylene, two stainless steel needles, two polycarbonate handles and two stainless steel needles molded with polycarbonate handles.

- **Indications for Use:**
  I-STOP® Trans Obturator Male / Female Sling is intended to be used as a sub-urethral sling implant for the treatment of male stress urinary incontinence post-prostatectomy. And for females: for the treatment of urinary stress incontinence due to intrinsic sphincter deficiency and/or intrinsic sphincter deficiency.

- **Comparison to predicate device:**
  This is exactly the same device than I-STOP (K051533) with the same knitted sling and the same needles and handles. The device is similar to the AMS Male Transobturator Sling System (K053371).

- **Summary of testing:**
  Mechanical tests, biocompatibility tests in compliance with ISO 10993 and chemical tests.

- **Summary of clinical tests:**
  Three studies on this surgical technique and three anatomical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CL Medical
% Mr. Vincent GORIA
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France

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Re: K063079
Trade/Device Name: I-STOP Trans Obturator Male/Female Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 2, 2006
Received: October 10, 2006

Dear Mr. GORIA:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K063079

Indications for Use

510(k) Number (if known): K063079

Device Name: I-STOP Trans Obturator Male / Female Sling

Indications for Use: I-STOP® Trans Obturator Male / Female Sling is intended to be used as a sub-urethral sling implant for the treatment of male stress urinary incontinence post-prostatectomy. And for females: for the treatment of urinary stress incontinence due to intrinsic sphincter deficiency 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)

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

510(k) Number K063079