

K971791

510(k) Summary

JUL 30 1997

Louisville Laboratories, Inc

Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension

1. Sponsor/Applicant name, address, telephone number,

Louisville Laboratories, Inc.
2400 Crittenden Drive
Louisville, Kentucky 40217
Telephone: (502) 634-5900
Facsimile: (502) 634-5959

Contact person:

Michael Campbell

Date of summary preparation

May 14, 1997

2. Device name

Trade/proprietary name: Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension
Common/usual name: Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension
Classification name: Manual Surgical Instruments
Urological Catheter

3. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed

The Louisville Laboratories, Inc. Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension is substantially equivalent to several devices on the market such as the Louisville laboratories Laparoscopic Bone Anchored Urethropexy Instrument Tray (K963076), the Laurus Medical Suturing System (K932553) and several surgical techniques that have been performed for over forty years.

4. **Device description**

The Laparotomy Bladder Neck Suspension Kit is comprised of a template assembly, suture retriever, suture cutter and suture pulling loop. The template assembly, suture retriever and suture cutter were cleared for marketing on April 4, 1997 under K963076, as part of the Louisville Laboratories Laparoscopic Bone Anchored Urethropexy Instrument Tray.

5. **Intended use**

The Louisville Laboratories, Inc. Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension is all intended for bladder neck suspension for female stress incontinence due to urethral hypermobility.

6. **A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device(s) cited**

The Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension is substantially equivalent to the Louisville Laboratories Laparoscopic Bone Anchored Urethropexy Instrument Tray and the Laurus Medical Disposable Suture Placement System. The technological characteristics are similar in that they include several kit components for delivering bone anchors and/or sutures for bladder neck suspension. Both the Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension and predicate devices are similar in design in that they both use a method or a component for positioning the sutures to the appropriate anatomical site. Both the Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension and predicate products are similar in that they use a standard scissors or a suture cutter for cutting the sutures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

JUL 30 1997

Re: K971791
Vaginal Suturing Kit for Lapartotomy
Bladder Neck Suspension
K971802
Vaginal Suturing Kit for Laparoscopic
Bladder Neck Suspension
Regulatory Class: II
Product Code: MBI
Dated: May 14, 1997
Received: May 15, 1997

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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.

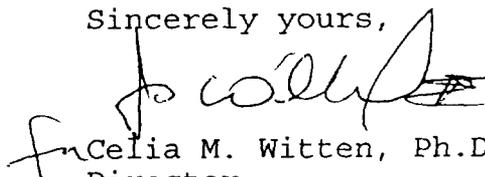
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K971791

Device Name: Louisville Laboratories, Inc Vaginal Suturing Kit For Laparotomy Bladder Neck Suspension

Indications For Use:

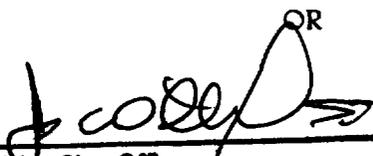
The Louisville Laboratories, Inc. Vaginal Suturing Kit for Laparotomy Bladder Neck Suspension is indicated for urethropexy procedures for bladder neck suspension to correct female stress incontinence due to urethral hypermobility.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971791

(Optional Format 1-2-96)

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