K971796

AUG 12 1997

510(k) Summary

Louisville Laboratories, Inc

Laparotomy Bladder Neck Suspension Kit With Bone Anchors

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:	Laparotomy Bladder Neck Suspension Kit With Bone Anchors
Common/usual name:	Laparotomy Bladder Neck Suspension Kit With Bone Anchors
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. Laparotomy Bladder Neck Suspension Kit With Bone Anchors is substantially equivalent to several devices on the market such as the Louisville laboratories Laparoscopic Bone Anchored Urethropexy Instrument Tray

(K963076), the Microvasive Percutaneous Bladder Neck Suspension Kit, (K931181, K931182, K932925) and several surgical techniques that have been performed for over forty years.

4. **Device description**

The Laparotomy Bladder Neck Suspension Kit With Bone Anchors is comprised of a template assembly, suture retriever, suture cutter, bone anchors 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. Laparotomy Bladder Neck Suspension Kit With Bone Anchors is 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 Laparotomy Bladder Neck Suspension Kit With Bone Anchors is substantially equivalent to the Louisville Laboratories Laparoscopic Bone Anchored Urethropexy Instrument Tray and the Microvasive Percutaneous Bladder Neck Suspension Kit. The technological characteristics are similar in that they include several kit components for delivering bone anchors for bladder neck suspension. Both the Laparotomy Bladder Neck Suspension Kit With Bone Anchors 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 Laparotomy Bladder Neck Suspension Kit With Bone Anchors and predicate products are similar in that they use a standard scissors or a suture cutter for cutting the sutures.

Louisville Laboratories

Premarket Notification
Truthful and Accurate Statement
for
Laparotomy Bladder Neck Suspension Kit with Bone Anchors

I certify that, in my capacity as Regulatory Affairs Specialist of Louisville Laboratories, I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Laparotomy Bladder Neck Suspension Kit with Bone Anchors are truthful and accurate and that no material fact has been omitted.

Signature

4/28/97
Date

David Phelps, Regulatory Affairs Specialist
Typed Name and Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 12 1997

Re: K971796
Laparotomy Bladder Neck Suspension Kit with Bone Anchors
Regulatory Class: II
Product Codes: EZL, MBI, HWC, HET
Dated: May 14, 1996
Received: May 15, 1997

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 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.

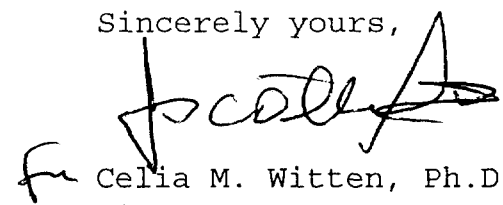
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 device 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 device as described in your 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 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 device, 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,



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

Enclosure

510(k) Number (if known): K971796

Device Name: Louisville Laboratories, Inc

Indications For Use:

The Louisville Laboratories, Inc. Laparotomy Bladder Neck Suspension Kit With Bone Anchors 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)

OR

Over-The-Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971796

(Optional Format 1-2-96)