JUN 2 5 2002

K021012

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: Quality Medical Solutions LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour
6-Date summary prepared: March 25th, 2002
7-Device Trade or Proprietary Name: Laminaria
8-Device Common or usual name: Laminaria digitata
9-Device Classification Name: Hygroscopic laminaria cervical dilator
10-Substantial Equivalency is claimed against the following device:

- Staol Laminaria Tents from Norscan Trading Group

11-Description of the Device:

This single use device is a hygroscopic laminaria cervical dilator designed to dilate (stretch open) the cervical os by cervical insertion of a cylindrical and expansible material into the cervical canal, made from the root of a seaweed (laminaria digitata). Laminaria expands when it absorbs moisture.
The ability to increase in size slowly (usually 6 to 24 hours) is of advantage in physiologically dilating a closed body orifice such as the cervical canal. When used improperly, it may cause the patient major discomfort or uterine complications
Laminaria is available in 2, 3, 4, 5, 6, 7, 8 and 9 mm diameter sizes with a length varying between 50 and 65 mm. Each laminaria is drilled and attached to a 75-95 mm string to facilitate removal from the cervical canal (the last digit of the product code reflects its size)
Laminaria is intended for use whenever it is desirable to dilate the cervical canal, such as uterine or suction curettage, labor induction, IUD placement and removal, and Radium placement

12-Intended use of the device:

Laminaria is intended for use whenever it is desirable to dilate the cervical canal, such as Uterine curettage, Labor induction, IUD placement and removal, and Radium placement

13-Safety and Effectiveness of the device:

This device (**Laminaria**) is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **Laminaria** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 951330
Attachments inside notification submission file	**VERY IMPORTANT: REFER TO TABLE WITHIN MAIN SUBMISSION FOR DETAILS**
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Similar (Ethylene Oxide but different parameters)
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2002

Mr. Jay Mansour
Director, Quality & Regulatory
Quality Medical Solutions, LLC
1308 Morningside Park Road
ALPHARETTA GA 30022

Re: K021012
Trade/Device Name: Laminaria 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic-Laminaria Cervical Dilator
Regulatory Class: II
Product Code: 85 HDY
Dated: March 26, 2002
Received: March 29, 2002

Dear Mr. Mansour:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K021012

Device Name: LAMINARIA

Indications For Use:

LAMINARIA IS INDICATED FOR USE WHENEVER IT IS DESIRABLE TO DILATE THE CERVICAL CANAL, SUCH AS UTERINE CURETTAGE, LABOR INDUCTION, IUD PLACEMENT AND REMOVAL, AND RADIUM PLACEMENT

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021012

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)