DEC 2 0 2002

ATTACHMENT 2

510(k) SUMMARY

K021115

(Revised)

GyneFlex

Common/Classification Name: Perineometer, 21 CFR 884.1425

Naissance Holdings, L.C.
4905 34th Street South
St. Petersburg, FL 33711

Contact: Suzanne B. Sloan
Nancy E. Taylor

Prepared: April 4, 2002
Revised: December 9, 2002

A. LEGALLY MARKETED DEVICE

The Colonial Medical Supply Pelvic Muscle Therapy was cleared for marketing on December 27, 2000, in premarket notification K002830. Naissance Holdings, L.C., submits this premarket notification for **GyneFlex**.

B. DEVICE DESCRIPTION

The **GyneFlex** is a pelvic floor muscle exerciser. The product has six ranges of resistance. Other than variation in resistance, each exerciser is identical, including identical indications and labeling.

It is a "v" sh aped device that provides resistance after insertion into the vagina when the patient contracts her pelvic muscles. The material is made of a polymer plastic specifically formulated to provide specific ranges of resistance for use as an adjunct to Kegel exercises.

C. INTENDED USE

The **GyneFlex** is recommended for the strengthening of the perineal muscles by offering resistance to an individual's vo luntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **GyneFlex** is substantially equivalent to the Colonial Medical Supply Pelvic Muscle Therapy, a perineometer, which was cleared for marketing on December 27, 2000, in premarket notification K002830.

The **GyneFlex** has indications for use that are similar to those as the legally marketed predicate device. Both the **GyneFlex** and the predicate device have identical indications concerning the strengthening of the pelvic floor muscles, which has been found to help women with incontinence, is consistent with 21 C.F.R. 884.1425. **GyneFlex** provides graduated resistance in specified ranges that help train the user in proper and effective pelvic floor muscle contractions and exercises, which is similar to the biofeedback provided by the predicate device.

E. TECHNOLOGICAL CHARACTERISTICS

The **GyneFlex** is a single, reusable, polymer plastic "v " shaped exerciser that exceeds the guidelines set forth in ISO 10993.

F. TESTING

Testing results indicate that the material is biocompatible, nontoxic and well tolerated by mucosal membranes.

G. CONCLUSIONS

This premarket submission has demonstrated that the **GyneFlex** is substantially equivalent to a device previously cleared for marketing by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Naissance Holdings, L.C.
% Ms. Eleanor A. Kolton
Greenburg Traurig, LLP
Attorneys at Law
800 Connecticut Avenue, Suite 500
WASHINGTON D.C. 20006

Re: K021115
Trade/Device Name: GyneFlex
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: 85 HIR
Dated: October 24, 2002
Received: October 28, 2002

Dear Ms. Kolton:

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

ATTACHMENT 3

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K021115

Device name: **GyneFlex**

Indications for Use:

The GyneFlex is recommended for the strengthening of the perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021115