K011488

FEB 22 2002

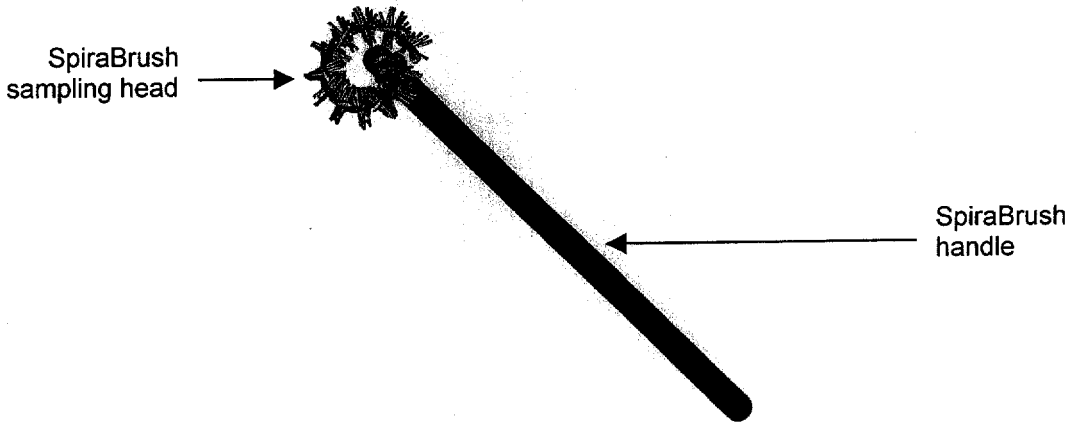
VIII. SUMMARY OF SAFETY & EFFECTIVENESS STATEMENT

SpiraBrush Indications for Use:
SpiraBrush Cx is intended for obtaining a biopsy of visible exocervical lesions for the purpose of obtaining a tissue diagnosis in women with intraepithelial disease. Tissue samples obtained by the SpiraBrush Cx biopsy instrument should be evaluated using a histologic technique.

Clinical Trials:
In clinical trials, the SpiraBrush CX biopsy instrument resulted in less frequent need for hemostasis as compared with the standard punch biopsy.

Procedure:

SpiraBrush Cx Biopsy Instrument is intended for obtaining a cervical biopsy of a suspicious area or visible exocervical lesion detected during vaginal examination. The patient is maintained in a standard lithotomy position during the SpiraBrush Cx Biopsy Instrument sampling.



SpiraBrush Biopsy Procedure

1. The head of the SpiraBrush® Cx Biopsy Instrument (see diagram) is placed directly onto the exocervical lesion or cervical area that is to be biopsied (handle will be at 90 degree angle to the cervix). The flat surface of the SpiraBrush head tip is to remain in contact with the cervical sampling area throughout the biopsy procedure.

2. Apply firm and steady pressure to keep the brush firmly placed on the cervix, and rotate the SpiraBrush at least three full rotations clockwise and three full rotations counter-clockwise or until micropunctate bleeding occurs and brush head is abundantly covered with a bloody-mucoid sample.

SpiraBrush Head Removal

1. After completion of the SpiraBrush cervical biopsy procedure, avoiding any unnecessary manipulation of the SpiraBrush's tissue sample, the SpiraBrush head is to be snapped off of the SpiraBrush handle

2. To snap the SpiraBrush head from the handle, the health care provider holds the handle between the fingers and the thumb, bending the handle at the scored mark (approximately 1 ¼ inches from the brush head).

3. Carefully, holding on to the SpiraBrush head and biopsy, the entire SpiraBrush head and biopsy is immediately dropped into a labeled bottle of alcohol-based cytology solution.

Post Biopsy Procedure Patient Follow Up

Post SpiraBrush biopsy cervical bleeding, if present, may be gently dabbed with cotton or gauze, applying gentle pressure to the cervix until bleeding stops. The vaginal examination can be resumed once bleeding has been controlled.

SpiraBrush Cx Biopsy Instrument Processing (Laboratory)

Cervical Biopsy Tissue Removal from SpiraBrush head:

1. After a suitable period of fixation in the alcohol-based cytology solution, the SpiraBrush head is to be manually removed from the cervical tissue specimen by trained tissue processing personnel.

2. Protective gloves and forceps are used for removal of the head of the SpiraBrush out of the preservative bottle. After the biopsy specimen has been removed from the head of the SpiraBrush, the head is discarded in an appropriate receptacle.

3. Cervical biopsy tissue still clinging to the head of the SpiraBrush can be manually removed by any of the following suggested methods:

   a. The SpiraBrush head is held by forceps over the preservative bottle, and agitated up and down in the preservative solution to remove visible tissue still clinging to the head. Tissue fragments are allowed to fall back down into the preservative solution.

   b. Forceps are used to manually pick the tissue away from the SpiraBrush head, dropping the fragments back into the preservative solution. However, if forceps are used to handle the actual biopsy tissue, care must be taken not to crush or distort the biopsy specimen between the tips of the forceps.

   c. The SpiraBrush head can be held just above the preservative bottle with forceps, and biopsy tissue flushed off of the head back down into the preservative solution using an additional flush of preservative solution.

4. Once the cervical biopsy has been separated from the SpiraBrush head, if necessary, the remaining cervical biopsy is re-suspended, in additional preservative fluid.

From this step on, the SpiraBrush Cx Biopsy Instrument specimen preparation proceeds per the standard practices of the processing facility's preparation of any other cervical biopsy.

SpiraBrush® Cx Biopsy Microscopic Interpretation

A cervical biopsy obtained by the SpiraBrush Cx Biopsy Instrument is intended to be microscopically classified according to currently accepted microscopic cervical biopsy classification. Such cervical biopsy classification systems include The Bethesda and modified Bethesda Systems

Clinical Trial

Population:

A population of 41 female subjects at 4 investigation sites scheduled for LEEP due to visible exocervical lesions had both a SpiraBrush Cx Biopsy and cervical punch biopsy prior to LEEP. 37 subjects (90%) completed all phases of the investigation and were able to be used for evaluation.

Conclusions:

The clinical trial supported that the SpiraBrush Cx Biopsy Instrument produced an adequate transepithelial cervical biopsy that was substantially equivalent to a standard cervical punch biopsy for producing a tissue specimen that a reviewing pathologists could utilize to arrive at a meaningful clinical diagnosis by accepted cervical classification systems. SpiraBrush Cx Biopsy safety and effectiveness was further supported by tissue confirmation by LEEP or conization. The SpiraBrush cervical biopsy also produced less pain and bleeding for patients then standard cervical punch biopsy.

Contraindications:

SpiraBrush Cx is contraindicated for use in the following patients:

1. Patients who are pregnant
2. Patients currently on anticoagulant therapy
3. Patients with known bleeding disorders

Warnings:

- Use of SpiraBrush Cx may cause bleeding requiring application of Monsel's solution or silver nitrate to establish hemostasis in cases where dabbing of biopsy site is not adequate.

- In the unlikely event that the brush head separates from the handle during sampling (at the scored mark), remove the handle from the vagina. Then using ring forceps, retrieve the brush head from the vagina. If sampling was complete and adequate

(abundantly covered with bloody-mucoid material), place sample in alcohol-based preservative solution for processing. If sampling was not completed or inadequate, obtain sample using another SpiraBrush.

Adverse Events
None known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Stewart A. Lonky, M.D.
Chief Medical Officer
The TRYLON Corporation
970 West 190th Street, Suite 850
TORRANCE CA 90502-1037

Re: K011488
Trade/Device Name: SpirabrushCx® Biopsy Brush
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code(s): 85 HFB-Gynecological Biopsy Forceps
85 HHT-Cervical Spatula
Dated: November 21, 2001
Received: November 26, 2001

Dear Dr. Lonky:

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

510(k) NUMBER (IF KNOWN): K011488

DEVICE NAME: SpiraBrush Cx

INDICATIONS FOR USE:

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(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) (Optional Format 1)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011488