K983181

NOV 16 1998

PREMARKET NOTIFICATION [510(k)] SUMMARY
for CYTOPREP®

TRADE NAME: CYTOPREP®

COMMON NAME: Cervical Brush

CLASSIFICATION NAME: Spatula, Cervical, Cytological (per 21 CFR 884.4530)

CLAIMING EQUIVELANCE TO: Cervex-Brush® (K930955) and Exact Touch (K915844)

DESCRIPTION OF CYTOPREP®:

CYTOPREP® consists of two parts, the handle and the head.

The handle is 214mm in length, cylindrical and on one end it carries the name of the product. On the other end , there are two recesses (female) to accommodate the bottom part of the head. These two recesses, along with a special edge (male) on the bottom of the head, secure the head. When the physician has inserted the head in the endocervical canal and is turning the handle to obtain sample cells, the head turns (follows the physician's manipulations) and there is no slippage. Tests made (see XI Performance for attached laboratory report), prove that it will be impossible for a bristle to break and remain in the patient's cervix and almost impossible for the head to accidentally separate from the handle and remain in the cervix.

The head consists of:

The "male" edge on the bottom that is secured in the handle recess (female), stabilizing the head on the handle;

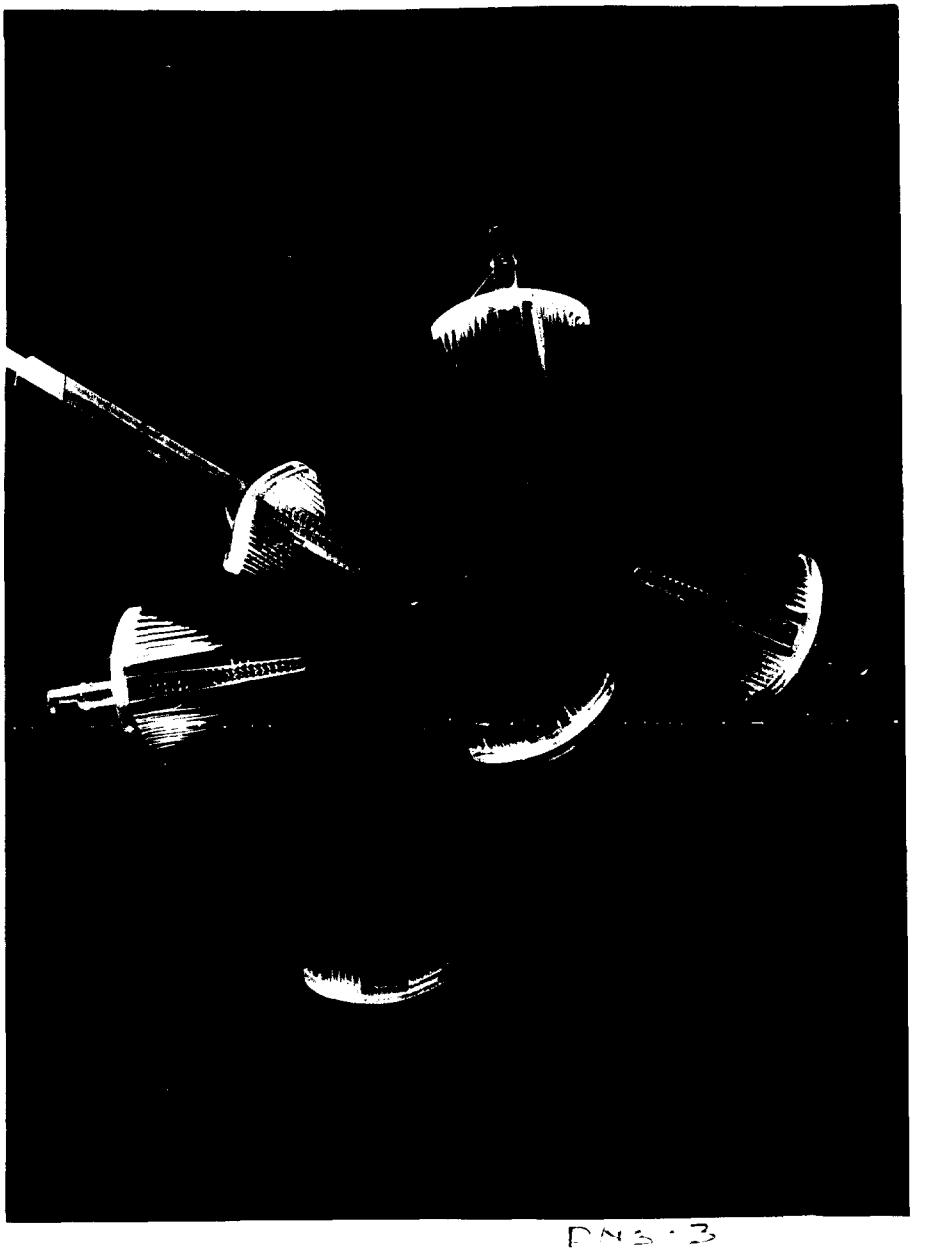
The base, upon which sit lengthy bristles on both sides of the center brush.

The center brush end sits upon the base of the head and its center stem extends beyond the lengthy bristles. On its center stem,

perpendicular to the lengthy bristles, sit bristles which extend from the base of the head to the end of the center stem.

On this page, please find a picture appropriately identifying the device and its two components.

CYTOPREP®:



PNS-3

INTENDED USE: The device is intended for the use of physicians and other professionals authorized to take sample cells from the cervix of the uterus, transfer them to a fluid suspension (or smear them on a slide, in the case of a traditional PAP test) for further preparation of cytological slides. **CYTOPREP®** was designed for use in conjunction with Liquid Based Cytology procedures. However, recent tests at the University of Munich, Germany, have proven it equally effective as a sampling device for the traditional PAP smear test.

TECHNOLOGICAL CHARACTERISTICS: Technologically, the device is an extremely difficult product to produce because it is of small size, the bristles extending from the base of the head and those as extending from the center stem are numerous and in numerous rows and the two groups of bristles are perpendicular to each other. To be able to produce it, new technology had to be developed by the manufacturer.

The two products to which equivalence is claimed have the following characteristics:

> Cervex-Brush® (K930955) - also consists of head and handle BUT the bristles of the head are only linear.
>
> Exact-Touch® (K915844) Is a single piece and its head has two almost perpendicular sets of bristles, BUT the two sets of bristles consist of only one row each, and the head appears to be quite hard.

A comparison of **CYTOPREP®** with the two products follows:

> **CYTOPREP®** vs. Cervex-Brush® (K930955)
>
> As stated above, both products consist of head and handle and they are similar in the way the head is attached to or removed from the handle. The two products are different in the head. The Cervex-Brush® head consists of lengthy bristles all running in the same direction. The manufacturer claims that the center portion of the head can enter the endocervical canal and thus be able to obtain sample cells from the exo-cervical area, transformation zone (T-zone) and endo-cervical canal.
>
> **CYTOPREP®** has bristles that run lengthwise on both sides of its center brush.... However, it also has the center brush that has small bristles

running perpendicular to the lengthwise bristles. In so doing, the center brush enters the endocervical canal and with its small bristles extracts sample cells from that region (much like the Cervex-Brush® does). Its lengthy bristles and center brush bristles extract sample cells from the T-zone. Finally, its lengthy bristles extract samples cells from the exo-cervical region.

The Cervex-Brush® (K930955) can easily deposit the cells it collected on a slide for the traditional PAP test. Its head can also be placed in the vial used for Liquid Based Cytology procedures. **CYTOPREP®** is designed for use in conjunction with Liquid Based Cytology. It is can also be used with the conventional PAP smear test procedure, where the sample cells are directly placed on the examination slide from the sampling device. Adequate care must be taken to obtain sample cells from all sections of the head of **CYTOPREP®**.

CYTOPREP® vs. Exact-Touch® (K915844)

The Exact-Touch® (K915844) is a one-piece device. As stated above it consists of one layer of bristles both in the base of its head as well as in its central stem. The manufacturer in a single operation of the mold achieves this one layer of bristles. **CYTOPREP®** has eight (8) layers of bristles on both sides of the central stem, consisting of 7 rows of bristles for each layer - 5 rows with 8 bristles, 1 row with 6 and 1 row with 4. The length of these bristles varies from 9mm to 2mm. Thus, each side consists of 50 bristles for a total of 100 bristles running lengthwise. By comparison, Exact-Touch® (K915844) has 11 bristles on either side of the center stem, for a total of 22 bristles. The length of these bristles runs the same for all 22 at 3mm.

CYTOPREP'S® center brush has 3 layers of bristles and 24 rows of bristles on two sides of its center stem for a total of 144 bristles. Their length varies but it is approximately 3mm, each. The center stem of Exact-Touch® (K915844) has 1 layer of bristles and there are 19 bristles on both sides of the stem for a total of 38. Their length also varies from 3-2mm.

In summary, the three products are the same in intended use and general construction. However, it is clear from the above descriptions of the products that the detailed technical formation of the **CYTOPREP®** head is uniquely formed and differs materially from the other two products.

CLINICAL PERFORMANCE DATA - There was no effort made to establish equivalence on the basis of clinical data between **CYTOPREP®** and the two products referred to above for the reasons mentioned below.

The validity of any cervical sampling device depends upon its ability to adequately sample the exo-cervical, T-zone and endo-cervical regions. To-date, it is considered that the presence of endo-cervical cells guarantees an adequate sample, which in turn results in the highest detection of epithelial abnormalities.

Scientific literature [1], [2] continuously reports that the best sampling technique that could be used in obtaining a "quality sample", is the use of two devices, Spatula and Cytobrush®. This sampling method, high in endo-cervical cell presence, gives superior detection results and is credited with the highest detection rates for CIN III (the last stage before invasive cancer) [1]. Please note that we make no claim that our device obtains a higher detection rate of CIN III. We claim that our device is capable of collecting endo-cervical sample cells in 93-95% of the cases, a level substantially higher than that achieved by conventional sampling techniques.

For these reasons, the studies made using the **CYTOPREP®** were directed toward confirming its performance against reported results of the most widely used sampling method, i.e., the combined use of Spatula and Cytobrush®.

CYTOPREP® has combined in one device those characteristics of the two devices reported as the best alternative (Spatula & Cytobrush®), which characteristics allow **CYTOPREP®** to obtain a "quality sample", high in endocervical cell presence, 93- 95% of the samples, and in total cell count equal to or exceeding the number of cells collected by the two aforementioned devices.

In (1), the study reports that the Cervex-Brush® alone is not as effective a device as the combined use of the Spatula and Cytobrush®.

CONCLUSIONS - On the basis of reports from physicians who have used more than 60,000 **CYTOPREP®** devices in the testing stage of the device's development and University of Geneva and independent laboratory studies, the following conclusions were reached:

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1. See ACTA CYTOLOGICA: Nov-Dec 1988, Vol. 32, No. 6, pp. 843-848

2. *ibid.*, May - June 1996, Vol.40, No. 3, pp.. 496-500

- The device is suited for between 85-90% of the patient population. Other devices have to be used for the 10-15% of the population due to the cervical stenosis of the cervix of these patients.
- The device causes no more discomfort or bleeding among the patients than the devices to which we seek equivalence.
- The device is capable of obtaining cells from the exo-cervix, T-Zone and endo-cervix.. Specific cell counts also showed that the device obtains a number of cells at least equal to that of two other devices combined (Spatula & Cytobrush®).
- **CYTOPREP®** is capable of obtaining endocervical sample cells from more than 93-95% of the samples.
- The morphology of the collected cells is maintained in 95% of the cells, as compared to 80% for the conventional sampling techniques.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 1998

Mr. K. G. Paganis
Vice,President-Compliance
CYTOPREP® Inc.
Renkwiler 593
FL-9492 Eschen LIECHTENSTEIN

Re: K983181
CYTOPREP® Cervical Brush
Dated: September 28,1998
Received: October 8, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HHI

Dear Mr. K. G. Paganis:

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 requirements, 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) 594-4613. Additionaliy, 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

519 (k) NUMBER (IF KNOWN): **K983181**

DEVICE NAME: **CYTOPREP®**

INDICATIONS FOR USE:

The device is used to sample the cervix of patients for the purpose of obtaining ecto-cervical, endo-cervical and T-zone sample cells. These sample cells are used for the "PAP" test.

While the product is designed to be used in conjunction with liquid based cytology procedure (monolayer method), it can also be used in conjunction with the traditional "PAP" test procedure.

(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 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983181