FEB 6 1998

K974301

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. [Separate Page]

I. Submitter: George Kuo, CLK International, Inc., 28 East Broadway, New York, NY 10002
Ph: 212-334-3953

II. Classification Names and numbers: Accessory to Ultrasonic Imaging System, IYO, Class II.

III. Common/Usual Name: Ultrasonic Probe Cover (Sheath)

IV. Proprietary Names: CLK™ Int'l, Sanitary Latex Probe Cover

V. Establishment Registration Number: In progress

VI. Classification: Probe covers such as these are regulated as accessories to the devices on which they are intended to be used. These covers are designed to be used on various probes of Ultrasound Imaging Systems, especially those used in transvaginal or transrectal imaging. Therefore, they are regulated as Class II devices. One of the major instrument types on which they are used is the Ultrasonic Imaging System, pulsed echo, described in CFR 892.1560. Because of some latex problems, they are also regulated as latex products, similar to exam gloves which are often used in same body areas.

VI. Performance Standard:
None established under section 514.

VII. Description of the Device:
These devices are latex sheaths, closely related to condoms which have been used in the past for this purpose. However, these sheaths have different dimensions, depending on which probe they are designed to be used. They may range in size from about 30 cm. length, and 10 cm. in diameter to 6 cm. in length to 2 cm. in diameter with the 20 cm x 5 cm being the most common.

VII. Substantial Equivalence: The CLK Latex Probe Cover is substantially equivalent to devices currently on the market, cleared by the 510(k) process. The CLK Latex Ultrasound Cover is substantially equivalent to (for example) the following devices:

1. Civco Latex Ultrasound Sheaths, cleared under K-895614, by Civco Medical Instruments,
2. Civco Probe Cover, cleared under K-943393 by Civco Medical Instruments,
3. Kiltex Probe Covers, cleared under K-961029, by Kiltex Corporation, and
4. Eclipse Probe Cover, cleared under K-953673, by Parker Laboratories.
5. Corometrics Sanitary latex Probe cover, cleared under K-900805 and/or K-920374 by Corometrics Medical Systems.

Characteristics of the CLK™ Latex Probe Covers are compared with those of other products currently on the market Table I.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to aid in avoiding contamination of ultrasonic probes by bodily fluids to facilitate cleaning of these probes. These are the same as those of the predicate devices. These products also have the same intended uses as similar products currently cleared for marketing by the 510(k) process.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market that are prepared from latex materials.

3. Descriptive information provided shows that the materials from which the CLK Ultrasound Probes are made are substantially equivalent to (nearly identical with) those of similar products, used for identical purposes, currently on the market. Tests show they meet the requirements of ASTM D3578-95 for latex exam gloves.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment V.

Data used in determining substantial equivalence include those required by ASTM D3578-95, and biocompatibility test data as required by Int. Std ISO-10993 as modified by the FDA in their General Program Memorandum #G95-1.

Summary of Test Data Used in Determining Equivalence:
Physical characteristics, before and after aging,
Biocompatibility characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 1998

George Q. Kuo, M.D.
President
CLK International, Inc.
28 East Broadway, 2nd Fl
New York, NY 10002

Re: K974301
CLK Int'l Sanitary Latex Probe Cover
Dated: January 7, 1998
Received: January 12, 1998
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Dr. Kuo:

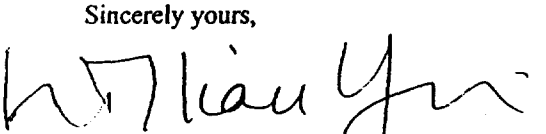
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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,



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

VIII.1 Indications for Use: [Separate Page]

510(k) Number: ~~###~~ K974301

Device Name: CLK™ Int'l. Sanitary Latex Probe Cover

1. Intended to be placed on Ultrasound Probes used in natural body orifices--such as the vagina--to facilitate cleaning and sanitization of the probe.

(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)

repl. pg. 4

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
(K) Number K974301