

JUL 10 1997

PROTEK
MEDICAL PRODUCTS INC.

May 1, 1997

Document Mail Center
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

SUMMARY
PREMARKET NOTIFICATION 510 (k)
FOR TRANSVAGINAL NEEDLE GUIDE
an ULTRASOUND TRANSDUCER ACCESSORY

SUBMITTER: Rick L. Pruter
COMPANY: PROTEK Medical Products Inc.
ADDRESS: 221 East Market Street
CITY: Iowa City
STATE: Iowa
COUNTRY: USA
CONTACT: Rick L. Pruter
PHONE: (319)358-8080
FAX: (319)339-8258

DATE SUMMARY PREPARED: May 1, 1997

Trade Name:

Trans vaginal Needle/Biopsy Guide for Ultrasound Transducers

Common Name:

Needle Guide, Puncher guide, Biopsy guide, Needle Guide system,
Endocavity Needle Guide

Classification Name:

Not Known

SUMMARY

COMMERCIALY PRODUCED PRODUCTS OF EQUIVALENCE:

Substantial Equivalence Comparison:

These new devices are the same as devices being legally marketed by several companies.

The new devices design, manufacturing, labeling and its intended uses are the same as many existing devices currently being marketed by Civco Medical Instruments, and Amedic among others. The only deviation is in the size and shape. Owner of this new company is co-inventor of these products and was an officer at Civco, one of the companies we are claiming substantial equivalence.

The following is a cross reference of products that will be identical:

New Device

<i>PROTEK Medical Inc</i>	<i>Civco</i>	<i>Civco's 510(k)</i>
1-535-0003 Guide	677-027	K875240/A
1-535-0004 Guide	6000-0022-1A	K875240/A

*Other part numbers vary only in size and shape

Commercially Produced Products of Equivalence:

There are several products of equivalence legally marketed by companies including the following:

Civco Medical from Iowa, USA

Amedic of Sweden, ,

GE Medical Wis. USA,

Other known companies that legally market this device:

ATL Bothell Washington

Siemens Medical Systems Isaque Washington

Diasonics San Jose Calif.

Toshiba Tustin, California

among others

Comparison: (see Comparison Chart Appendix D-1)

These devices are similar to several predicate devices legally marketed in respect to the materials, packaging, distribution and intended use. There are several hundred different configurations that Civco and Amedic are currently legally marketing for the (OEM)original equipment manufacturers. The original equipment manufacturers also legally markets these devices. This notification compares our product with Civco,s and Amedic and GE Medical.

These new products have the same intended use as legally marketed devices. The same end users. The same material manufactures and the same people that tested and processed Civco's legally marketed devices.

SUMMARY

DEVICE DESCRIPTION:

Narrative Description:

A tube, a cannula that is an accessory that snaps or rests (depending on configuration) onto an ultrasound transducer (884.2960)

A disposable, single use, sterile tube that helps direct a needle, biopsy or catheter to a target working in conjunction with an ultrasound transducer and system

Device Physical Specifications:

A stainless steel cannula or plastic tube with a small clip or bracket for locating and securing. Dimensions and designs vary and are specified with the original equipment manufacturer of ultrasound systems and transducers

Intended use:

1. Used to assist doctors when performing a vaginal biopsy
2. Used to guide a needle, biopsy or catheter into the vaginal gland.
3. Used as an accessory in conjunction with an ultrasound transducer (884.2960)
4. Used as an accessory in conjunction with Ultrasound systems (892.1560)
5. Used to improve needle placement vs. guiding needle with the finger

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

(SEE ATTACHED CHART - APPENDIX D)

Appendix D in SUMMARY**Substantially Equivalence Comparison Chart With
Civco Medical 510(k) #K875240/A**

<u>Description</u>	<u>PROTEK Medical Products Inc.</u>	<u>Civco Medical</u>
Indications for use	Ultrasound transducer needle guide (accessory)	Ultrasound transducer needle guide
Target Population	Doctor's	Doctor's
Designed by	OEM. Doctor. PROTEK	OEM. Doctor. Civco
Design	Sizes & Shapes Varies	Sizes & Shapes Varies
Materials	Stainless steel Medical grade plastic	Stainless steel Medical grade plastic
Performance	Target fixtures Mil Std 105E	Target Fixtures Mil Std 105E
Sterility	ETO	ETO
Mechanical Safety	end product tests	end products tests
Chemical Safety	No Hazardous Components 29CFR 1910.1200	No Hazardous Components 29CFR 1910.1200
Anatomical Sites	Where Ultrasound is Used	Where Ultrasound is Used
Disposition	Disposable	Disposable
Where Used	Hospitals & Clinics	Hospitals & Clinics
Standards Met	Mil Std 105E on voluntary standards	Mil Std 105E on voluntary standards
Electrical Safety	No Electrical Components	No Electrical Components
Manufacturing Method	Injection molded clips and purchased surgical tube	Injection molded clips and purchased surgical tube
Packaging	TYVEK "Chevron Peel Pouch"	TYVEK "Chevron Peel Pouch"
Human Factor	No Known Adverse Effects	No Known Adverse Effects

*OEM definition: Original Equipment manufacturer of Ultrasound Systems(892.1560)
including Ultrasound Transducer manufacturers (884.2960)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1997

Rick L. Pruter
President / CEO
PROTEK Medical Products, Inc.
221 E. Market, Suite 291
Iowa City, Iowa 52245-2166

Re: K971722
1-535-0003 Transvaginal Needle Guide for Shimadzu
and 1-535-0004 Transvaginal Needle Guide for
Acoustic Imaging, Inc.
Dated: May 5, 1997
Received: May 9, 1997
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Pruter:

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. 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 registration, listing of devices, good manufacturing practices, 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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (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.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

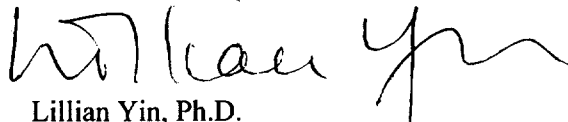
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

Page 2 - Mr. Rick Pruter

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) 594-4591. 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 at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin". The signature is fluid and cursive, with the first name "Lillian" written in a larger, more prominent script than the last name "Yin".

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(s)

510(k) Number (if known) K971722

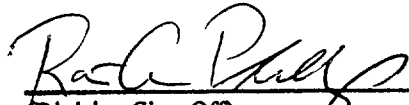
Device Name: Trans Vaginal Needle Guide

Indication for Use: _____

**Accessory-Needle Guides used for Vaginal Ultrasound Transducers
for performing Vaginal Biopsies.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K971722

Prescription Use X
(Per 21 CFR 801.109)

OR

Over The Counter Use

(Optional Format 1-2-96)