JUN 8 1999

K990913

510(K) Summary

March 9, 1999

1) PRODIMED Laboratories
c/o Washington Regulatory Services
Randolph L. Cooke
23 Welisewitz Road
Ringoes, NJ 08551
609-466-0510
Fax 609-466-4443

2) DEVICE NAME:

Proprietary Names:

HOC SET with valve
HOC SET without valve
HOC SET with valve – Soft plug
HOC SET without valve – Soft plug

OPS without valve
OPS with valve
OPS double lumen

Luer Lock Needle 30 cm
Luer Lock Needle 25 cm or any specified length

Common Name: Assisted Reproduction Needles

Classification Name: Assisted Reproduction catheters are classified as Class II at 21 CFR 884.6100. The product code is 85 MQE.

3) IDENTIFICATION: These devies have been down classified FR Vol 63, No. 175 September 10, 1998. Effective date: October 13, 1998.

4) DESCRIPTION OF DEVICE:

H.O.C. Set™ Hazout oocyte collector with or without valve
Needle: 30 cm; O.D. 17 gauge, I.D. 18 gauge, echogenic tip
Optional: 3-way valve

The device features a simple flux metallic needle, 30 cm in useful length, 17 gauge in outside diameter and 18 gauge in inside diameter, with double-

chambered point and echogenic distal tip on two centimeters for easier ultrasound guidance.

The needle is placed in a teflon packing tubing for protection. A teflon-cast catheter carries the aspirated follicular fluid to a 30 ml round-bottomed vial fitted with a screw-cap, or to a 30 ml round-bottomed vial fitted with a flexible cap (model HOC Set 2).

The model with a three-way valve set between the puncture needle and the collecting vial allows suction and rinsing of the follicles in turn.

Packaging: Disposable device in single unit blister packaging.
Irradiation sterilized.
Available in 5 unit packs.
H.O.C. vials are also sold alone by 50 units.

O.P.S. Oocyte Puncture Set™
Needle: 30 cm; O.D. 17 gauge, I.D. 18 gauge, echogenic tip

The device features a simple flux metallic needle, 30 cm in useful length and 17 gauge in outer diameter and 18 gauge in inside diameter, with double-chambered point and echogenic distal tip on two centimeters for easier ultrasound guidance. The device must be connected to an irradiation sterilized Falcon tube.

The needle is placed in a teflon packing tubing for protection. A teflon-cast catheter carries the aspirated follicular fluid to a Falcon tube.

Packaging: Disposable device in single unit blister packaging.
Irradiation sterilized.
Available in 5 unit packs.

Luer-lock Needle for Ovum recovery
Needle: 25 cm or 30 cm; O.D. 17 gauge, echogenic tip; I.D. 18 gauge

Simple flux steel needle, 17 gauge in outside diameter and 18 gauge in inside diameter, with double-chambered point and echogenic distal tip on two centimeters for easier ultrasound guidance.

Two sizes: 25 cm or 30 cm long.
The needle has a Luer-lock to attach a syringe, and a green plastic inner madrel. The needle is placed in a Teflon packing tubing for protection.
Packaging: Disposable device in single unit sealed bag.
Irradiation sterilized.
Available in 10 unit packs.

Function of Devices/Significant Physical Characteristics of Device:
Both the H.O.C. Set™ (Hazout oocyte collector, with or without a valve) and the O.P.S. Oocyte Puncture Set™ procedures achieve a safe and effective recovery of a maximum ova, eliminating the risks of traumatic handling of the ovum that would be detrimental to zona pellucida integrity, thus insuring optimal operating conditions for ovum conservation and better fertilization rate.

The Luer-lock Needle for ovum recovery acts as a laparscopic or ultrasonographic ovum recovery device (transvesical, transvaginal, periurethral or endovaginal).

Device Design/ Material Used/ Physical Properties:

HOC SET:

Device Part	Material Used
Needle	Metal
Fitting	Polyamide
Collect tube	
Vacuum tube	Polyether amide
Plug	Polyethylen
Tape	Polycarbonate
Collect ube	Butadien styren

OPS SET:

Device Part	Material Used
Needle	Metal
Fitting	Polyamide
Collect tube	
Vacuum tube	Polyetreamid
Plug	
Tape	Polycarbonate

Luer-lock Needles:

Device Part	Material Used
Needle	Metal
Fitting	Polyamide
Mandrel	Polyamide

5) STATEMENT OF INTENDED USED

These devices are used to introduce or remove gametres, zygotes(s), preembryo)s) and/or embryo(s) into or from the body.

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HOC SET without valve
HOC SET with valve – Soft plug
HOC SET without valve – Soft plug

OPS without valve
OPS with valve
OPS double lumen

Luer Lock Needle 30 cm
Luer Lock Needle 25 cm or any specified length

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 1999

PRODIMED Laboratories
c/o Washington Regulatory Services
Mr. Randolph L. Cooke
23 Welisewitz Road
Ringoes, N.J. 08551

Re: K990913
PRODIMED Assisted Reproduction Needles
Dated: March 11, 1999
Received: March 18, 1999
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

Dear Mr. Cooke:

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 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). 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. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) K990913

DEVICE NAME: Prodimed Assisted Reproduction Needles

INDICATIONS FOR USE:

These devices are used to introduce or remove gametres, zygotes(s), preembryo)s) and/or embryo(s) into or from the body.

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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 CFE 801.109 (Options Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990913