DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 1999

Ms. Elizabeth Platt
Regulatory Affairs Supervisor
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K984604
Trade Name: Architect™ Estradiol MasterCheck
Regulatory Class: I
Product Code: JJX
Dated: December 21, 1998
Received: December 28, 1998

Dear Ms. Platt:

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

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAY 27 1999

K983604

510(K) Summary March 3, 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: Prodimed Intra-uterine, Intra-fallopian Transfer Assisted Reproduction Catheters

Intra-uterine transfer
1) Frydman Catheter 4.5, 5.5
2) Frydman Catheter 4.5 with 2 lumen and removable mandrel
3) Long Frydman Set
4) Frydman Set
5) Soft Frydman Set
6) Soft Frydman Set with madrel
7) TDT Set

Intra-fallopian transfer
1) Biset for GIFT
2) Gift Catheter
3) Oliver Set
4) Rinsing Valve for Oliver Set

Common Name: Assisted Reproduction Catheters

Classification Name: Assisted Reproduction catheters are classified as Class II at 21 CFR 884.6110. The product code is 85 MQF.

3) IDENTIFICATION: The Assisted Reproduction microtool devices have been down classified FR Vol. 63, No. 175 September 10, 1998. Effective date: October 13, 1998.

4) DESCRIPTION OF DEVICE:
As found in the labeling/promotional material:

Frydman™ Catheter
Polyethylene catheter with a flexible end, internal diameter: 1.1mm, outer diameter: 1.6mm, and a distal opening.

For the 4.5 model:
- Length of flexible end: 4.5cm
- Total length: 17.5cm
- Two hysterometric markings at 5.5 and 6.5cm from the end

For the 5.5 model:
- Length of flexible end: 5.5cm
- Total length: 18.5cm
- Two hysterometric markings at 6.5 and 7.5cm from the end

Double Lumen Frydman™ Catheter 4.5
- Polyethylene catheter, 17.5cm long, consisting of a central tube 2.1mm, stiffened in its proximal part on 13cm by a second polypropylene tube 2.6mm, with two hysterometric markings at 5.5 and 6.5 from the distal opening.
- The central tube is a double lumen tube: its lateral lumen is provided with a malleable mandrel, and its central lumen 1.1mm, is intended to contain embryo(s).

Soft Frydman™ Set (with or without mandrel)
The set includes 2 catheters:
- Catheter N° 1: Polypropylene introducer (with a blue adapter)
  - 14.5 cm long
  - 2.2mm with positioning markings at 1, 2, 3, 4, 5, 6 and 7 cm from its distal end
  - with a movable sliding stopper
- Catheter N°2 Polyurethane reimplantation catheter
  - 23 cm long
  - 1.53mm, 0.7mm
  - with markings spaced 1 cm apart in its lower part
  - with a white adapter locked by a polyethylene cap
- Mandrel, 17.5 cm long, depending on the model

Short Frydman™ Set (for difficult embryo transfer)
The set includes 2 catheters:
- Catheter No. 1 polypropylene introducer (with an blue adapter)
  - 14 cm long
  - 2.2mm, with positioning markings at 1, 2, 3, 4, 5, 6 and 7 cm from its distal end
  - with a green mandrel and a movable sliding stopper
- Catheter No. 2 polyethylene reimplantation catheter (with an orange adapter)
  - 21 cm long
  - 1.6mm, 1.1mm

- with a steel tube and 3 markings spaced 1 cm apart in its lower part

Long Frydman™ Set (for difficult embryo transfer)
The set includes 2 catheters:
- Catheter No. 1 polypropylene introducer (with an blue adapter)
  - 20 cm long
  - 2.2mm, with positioning markings at 1, 2, 3, 4, 5, 6 and 7 cm from its distal end
  - with a green mandrel and a movable sliding stopper
- Catheter No. 2 polyethylene reimplantation catheter (with an orange adapter)
  - 25.5 cm long
  - 1.6mm, 1.1mm
  - with 1 marking its lower part

T.D.T.™ Set (for difficult embryo transfer)
The set includes 2 catheters:
- Catheter No. 1 polypropylene introducer
  - 17.5 cm long, with a flexible tip of 4.5 cm long, and two hysterometric markings at 5.5 and 6.5 cm from this end
  - It is provided with a plastic coated metal mandrel. Two models are available: with transparent mandrel or green mandrel.
- Catheter No. 2 ultra-thin polyethylene reimplantation catheter
  - 23.5 cm long, on a steel microtube, 1.0mm, 0.6mm, with a positioning mark at 2 cm from its lower part.

BI SET™ for GIFT
The set includes 2 catheters:
- Catheter No. 1 introducer (with an blue adapter)
  - 20 cm long
  - with positioning markings at 1, 2, 3, 4, 5, 6 and 7 cm from its distal end
  - with a green mandrel and a movable sliding stopper
- Catheter No. 2 polyethylene reimplantation catheter (with an orange adapter)
  - 25.5 cm long
  - 1.6mm, 1.1mm
  - with a steel tube and 1 marking at 2 cm from its lower part, with a movable stopper and a graduated protective sheath
- Stainless steel trocar (with green adapter), 20 cm long

Two models are available:
- 1 transfer catheter
- 2 transfer catheters

Oliver Set MK II ™
The set includes:
- 1 polyamide, echogenic, introducer, 24 cm long, 1.9mm, 1.1mm, pre-curved at 45°, with an loive-shape tip fitted with a ground stainless steel ring

- 1 metal mandrel, 27 cm long, 1mm. The introduction of this mandrel in the introducer allows to stiffen it and to insert it more easily.
- 1 polyethylene transfer catheter, 33 cm long, 1mm, 0.6mm. When this catheter is inserted in the introducer, its end protudes on 6 cm from the inrtoducer tip.

It is provided with a positioning system (markings) that allows to transfer at a chosen distance from the olive.

Function of Device/Significant Physical Characteristics of Device:
All devices are malleable, to allow a change in shape for the device; the mandrel is accluded to prevent the in-flow of bodily fluids when inserting into the crevix. All devices contain echolocater ultrasound markers.
The Frydman™ Catheter is used for embryo transfer when the permeability of the cervical canal is normal.
The Double Lumen Frydman™ Catheter 4.5 is used for embryo transfer with any permeability of the cervical canal.
The Soft Frydman™ Set, with or without a mandrel, is used for embryo transfer. The model with the mandrel may be used in the presence of a narrow or curved cervix that makes it difficult to introduce the model without the mandrel.
The Short Frydman™ Set is used for difficult embryo transfer. The set may be used in the presence of a narrow or curved cervix that makes it difficult to introduce a standard Frydman™ catheter.
The Long Frydman™ Set is also for difficult embryo transfer. The set may be used in the presence of a narrow or curved cervix that makes it difficult to introduce a standard Frydman™ catheter.
The T.D.T.™ Set is used for embryo transfer. The T.D.T.™ Set allows the reduction of the risk of setting in the crypts or occlusion by mucus that would impede the expulsion of the embryo.
The BI SET™ for GIFT is used for intrafallopian transfer of gametes via transparietal route under celioscopy.
The Oliver Set MK II ™ is used for intratubal transfer of gametes or zygotes via a transcervical approach.

Device Design/ Material Used/ Physical Properties:

Frydman Catheter:

Device Part	Material Used
Tube E212	Polyethylene
Tube E321	Polypropylene
Tube E320	Polypropylene
Tube E342	Polypropylene
Fitting	Polyethylene

Frydman Set:

Device Part	Material Used
Tube E212	Polyethylene
Tube X092	Stainless steel
Fitting	Polyethylene
Tube	Polypropylene
Fitting	Polypropylene
Tube E212	Polyethylene
Tube 063	Metal
Plug	Polypropylene

Frydman Soft:

Device Part	Material Used
Tube E212	Polyurethane
Fitting	Polyurethane
Tube	Polypropylene
Fitting	Polypropylene
Tube E212	Polyethylene
Tube 063	Metal
Plug	Polyethylene

TDT Set:

Device Part	Material Used
Tube E241	Polyethylene
Tube INOX	Stainless steel
Fitting	Butadiene styrene
Tube E212	Polyethylene
Tube E321	Polypropylene
Tube 320	Polypropylene
Tube 342	Polypropylene
Fitting	Polypropylene
Tube E212	Polyethylene
Tube 063	Metal
Plug	Polyethylene

Oliver Set:

Device Part	Material Used
Tube E241	Polyethylene

Tube INOX	Stainless steel
Fitting	Butadiene styrene
Tube	Polyamide
Fitting	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.

Intra-uterine transfer
- Frydman Catheter 4.5, 5.5
- Frydman Catheter 4.5 with 2 lumen and removable mandrel
- Long Frydman Set
- Frydman Set
- Soft Frydman Set
- Soft Frydman Set with madrel
- TDT Set

Intra-fallopian transfer
- Biset for GIFT
- Gift Catheter
- Oliver Set
- Rinsing Valve for Oliver Set

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

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

Re: K983604
Prodimed Intra-uterine, Intra-fallopian Transfer
Assisted Reproduction Catheters Sets
Dated: March 11, 1999
Received: March 15, 1999
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQF

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.

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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) K983604

DEVICE NAME: Prodimed Intra-uterine, Intra-fallopian Transfer Assisted Reproduction Catheters

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.

Intra-uterine transfer

1) Frydman Catheter 4.5, 5.5
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1) Biset for GIFT
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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 K983604