JUN 8 1999

K983713

510(K) Summary February 23, 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 Microinjection Pipettes

Common Name: Assisted Reproduction Microtools

Classification Name: Assisted Reproduction catheters are classified as Class II at 21 CFR 884.6130. The product code is 85 MQH.

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:

Quality and Security:
- Permanence and reproducibility of production
- Manufactured according to ISO 9001 and EN 46001 standards
- Routine performance of tests with revelation of biological indicators, search for endotoxins and embryotoxicity tests

Performance: (Function)
- Clear view and full control of the sperm for precision manipulation
- Bevel equipped with a short, sharp spike for easy, non-traumatising penetration of the oocyte
- Effective prehension by the holding pipettes to avoid rotation of the oocyte during the micro-injection

Ergonomics:
- Totally safe transport of pipettes thanks to a patented protective stand
- Easy, safe handling by simply pressing the base of the instrument between the thumb and index finger

Wide Range:

- Standard availability of pipettes with spike and 8µm opening, straight or curved at 20° and 30°
- Availability on order of spiked or non-spiked pipettes, opening of 6µm, or 8µm, straight or curved at 20° and 30°
- Wide choice suitable for every type of installation on all microscopes and instrument stands

UNILAM:

- Ready-to-use and easy to handle device
- Provides rapid location of the oocyte
- Guaranteed sterility of pipettes and perfect visibility
- Adapted to heating plates in order to keep the most convenient temperature for gamete survival

Function of Device/Significant Physical Characteristics of Device:
The holding and injection pipettes were made from 30µl borosilicate glass capillary tubes, 78mm in length and with inner and outer diameters of 0.69 and 0.97mm respectively. The glass pipettes were obtained by drawing thin-walled glass capillary tubes using a horizontal microelectrode puller. The holding pipette was cut and fire-polished on a microforge to obtain an outer diamter of 50µm and an inner diameter of 20µm. To prepare the injection pipette, the pulled capillary was opened on a microgriner to an outer diameter of 7µm and an inner diameter of 5µm; the bevel angle was 45°. This grinding step required ~3 minutes. The whetstone of the grinder was humidified by a slow water drip during the procedure. The microforge was then used to make a sharp spike on the injection piepette and to bend the edge of the holding and injection pipettes to an angle of ~35° to facilitate the injection procedure in the Petri dish.

Device Design/ Material Used/ Physical Properties:

Micro-Injection Pipettes: N51-A

Device Part	Material Used
Borasilicate Glass	Borone Oxide
	Sodium Oxide

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.

MICRO-INJECTION PIPETTES – Box of 10 units

13810008 Opening 8µm with Spike Straight

13812008 Opening 8µm with Spike Angle 20°
13813008 Opening 8µm with Spike Angle 30°

HOLDING PIPETTES – Box of 10 units

13900015 Opening 15µm Straight
13902015 Opening 15µm Angle 20°
13903015 Opening 15µm Angle 30°
1303200 UNILAM

SPECIAL MANUFACTURING

MICOR-INJECTION PIPETTES – Box of 10 units
Delivery delay of 8 weeks after confirmation order

13800008 Opening 8µm without Spike Straight
13802008 Opening 8µm without Spike Angle 20°
13803008 Opening 8µm without Spike Angle 30°
13810006 Opening 6µm with Spike Straight
13812006 Opening 6µm with Spike Angle 20°
13813006 Opening 6µm with Spike Angle 30°
13800006 Opening 6µm without Spike Straight
13802006 Opening 6µm without Spike Angle 20°
13803006 Opening 6µm without Spike Angle 30°

6) TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE:

Design Material:
ICSI Injection: Intracytoplasmic injection micropipettes are prepared from borosilicate glass tubing (OD: 1mm ID: 0,75m)

ICSI Holding: Intracytoplasmic injection micropipettes are prepared from borosilicate glass tubing (OD: 1mm ID: 0,75m)

Chemical Composition

Borasilicate Glass:	Boron Oxide	ACGIH TLV	10mg/m^3
		OSHA PEL	15mg/m^3
	Sodium Oxide	ACGIH TLV	Not Recommended
		OSHA PEL	Not Regulated

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, Inc.
Mr. Randolph L. Cooke
23 Welisewitz Road
Ringoes, N.J. 08551

Re: K983713
Prodimed Microinjection Pipettes
Dated: March 11, 1999
Received: March 15, 1999
Regulatory Class: II
21 CFR 884.6130/Procode: 85 MQH

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) K983713

DEVICE NAME: Micro-Injection Pipettes

INDICATIONS FOR USE:

These devices are used for I.C.S.I. (Intra cytoplasmic sperm injection)

MICRO-INJECTION PIPETTES – Box of 10 units

13810008	Opening 8µm with Spike Straight
13812008	Opening 8µm with Spike Angle 20°
13813008	Opening 8µm with Spike Angle 30°

HOLDING PIPETTES – Box of 10 units

13900015	Opening 15µm Straight
13902015	Opening 15µm Angle 20°
13903015	Opening 15µm Angle 30°

1303200 UNILAM

SPECIAL MANUFACTURING
MICOR-INJECTION PIPETTES – Box of 10 units
Delivery delay of 8 weeks after confirmation order

13800008	Opening 8µm without Spike Straight
13802008	Opening 8µm without Spike Angle 20°
13803008	Opening 8µm without Spike Angle 30°
13810006	Opening 6µm with Spike Straight
13812006	Opening 6µm with Spike Angle 20°
13813006	Opening 6µm with Spike Angle 30°
13800006	Opening 6µm without Spike Straight
13802006	Opening 6µm without Spike Angle 20°
13803006	Opening 6µm without Spike Angle 30°

(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 K983713/S001