K980814

JUN 23 1998

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EXHIBIT 2

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Contact: Paul V. Holmes ***MSc, PhD, DrMedSc.,*** General Manager

February 27, 1998

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: *PureSperm®*
   Classification Name/Product Code: 85 MQL(Cervical Cap per 21 CFR 884.5250)
   Common/Usual Name: Sperm Separation Medium

2. Equivalent legally marketed devices: ISolate: K971809, Modified Ham's F-10: K894432, Sperm Select: K872849.

3. Indications for Use (intended use) The product is intended to be used for the separation and purification of human sperm by density gradient centrifugation for intrauterine insemination (IUI).

4. Description of the Device: The product ***PureSperm®*** is a based on a buffered salt solution which contains a colloidal suspension of silica particles, with hydrophilic silane covalently bound to the particles. The pH, osmolality and salts of ***PureSperm®*** are formulated to be compatible with human sperm during their centrifugal separation and purification. The product is packaged in three bottle sizes, 100, 250 and 1000 mL, and these bottles, being Type I borosilicate glass, are packaged individually in white virgin-fibre cartons. Both the bottles and the cartons have pharmaceutically approved labels showing batch number, production date and expiration date. In addition, every carton contains an insert with a full description of the product, including instructions for use and precautions.

5. Safety and Effectiveness, comparison to predicate devices. The results of clinical trials and comparative testing against predicate products indicates that the new device is as safe and effective as the predicate devices.

6. Conclusion: Based on the similarity of composition, product testing results, and intended use, ***PureSperm®*** is substantially equivalent to the predicate devices named above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1998

Nidacon Laboratories
c/o Daniel Kamm
Regulatory Engineer
Kamm and Associates
P.O. Box 7007
Dearfield, IL 60015

Re: K980814
PureSperm® (Sperm Separation Medium)
Dated: May 18, 1998
Received: June 2, 1998
Unclassified/Procode: 85 MQL

Dear Mr. Kamm:

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 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,

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

j) Indications for Use

510(k) Number K980814

Device Name: ***PureSperm***® Sperm separation medium, Density gradient centrifugation medium

Indications for Use: The product is intended to be used for the separation and purification of human sperm by density gradient centrifugation for intrauterine insemination (IUI).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Sathing
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980814

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)