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EXHIBIT 2

NidaCon International AB
Mölndalsvägen 22
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Tel +46-31-405440
Fax +46 31-405415

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

June 7, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: ***PureSperm*® Buffer**
   Classification Name/Product Code: Reproductive Media and Supplements (21 CFR 884.6180) Procode: 85 MQL
   Common/Usual Name: Assisted Reproduction Media

2. Equivalent legally marketed devices: **K000621, SpermRinse™**

3. Indications for Use (intended use) The product is intended to be used for diluting PureSperm® (K980814 and K984172) sperm separation medium to prepare the different layers of a density gradient. PureSperm® Buffer has been formulated to optimize the function of the original PureSperm®..

4. Description of the Device: Buffer PureSperm® Buffer is supplied as a sterile (autoclaved SAL 10-3) isotonic salt solution. It is optimised for the dilution of PureSperm® or PureSperm® 100 in the preparation of density centrifugation gradients for separating and purifying human sperm. Two layers are commonly used for the gradient: 40% and 80%. This system effectively isolates the best sperm from lymphocytes, epithelial cells, abnormal or immature sperm, cell debris and bacteria.. PureSperm® Buffer is CE marked in countries of the European Union. It is supplied in 100 and 250 ml bottles.

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

7/10/2001

JUL 12 2001

NidaCon International AB
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K011606
PureSperm® Buffer
Dated: May 22, 2001
Received: May 24, 2001
Regulatory Class: II
21 CFR §884.6180/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 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) 594-4639. 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" (21CFR 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

j) Indications for Use

510(k) Number K011606

Device Name: *PureSperm*® Buffer

Indications for Use: The product is intended to be used for diluting ***PureSperm®*** (K980814 and K984172) sperm separation medium to prepare the different layers of a density gradient. PureSperm® Buffer has been formulated to optimize the function of the original PureSperm®.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011606