NOV 8 2002

K023206

EXHIBIT 2

NidaCon International AB
Mölndalsvägen 22
S-412 63, Göteborg, Sweden
Tel +46-31-405440
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Contact: Paul V. Holmes ***MSc, PhD, DrMedSc.***, General Manager

September 23, 2002

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: ***Sperm CryoProtec™***
   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: **Medi-Cult Sperm Freeze Medium Cat. No. 1067, K991333**

3. Indications for Use (intended use) The product is intended to be used cryopreservative for protecting human sperm during cryopreservation, an adjunct to one of the techniques for ART (assisted reproductive technology).

4. Description of the Device: Sperm CryoProtec™ is a buffered salt solution containing human serum albumin and glycerol (10%), has a stable shelf-life of at least 12 months in the unopened bottle at ambient temperature. The product has extremely low endotoxin levels, protects sperm during cryopreservation, and is produced according to cGMP (pharmaceutical device registration). No material of animal origin is included in the product and no antibiotics are present, since antibiotics can have a detrimental effect on sperm. Glycerol, which is also toxic to sperm, is present at the lowest concentration found to be compatible with a cryoprotectant effect.

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, ***Sperm CryoProtec™*** 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

NOV 8 2002

NidaCon International AB
% Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K023206
Trade/Device Name: Sperm CryoProtec™
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: September 23, 2002
Received: September 25, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

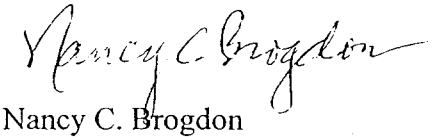
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K033206

Device Name: ***Sperm CryoProtec™***

Indications for Use: The product is intended to be used cryopreservative for protecting human sperm during cryopreservation, an adjunct to one of the techniques for ART (assisted reproductive technology).

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033206