

510(k) Summary**K131145**

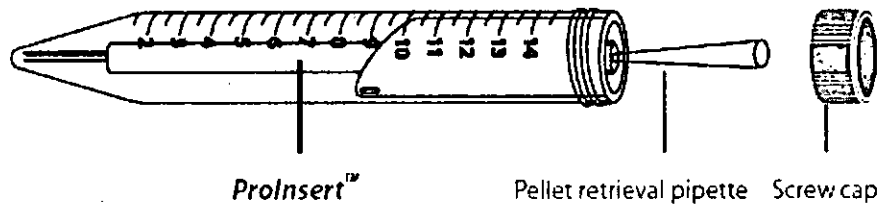
Nidacón International AB
Flöjelbergsgatan 16 B SE-431 37 Mölndal Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.se

**Date Prepared:** February 13, 2014**Contact:** Magda Alic Holmes, Vice President**Tradename:** ProInsert™**Common Name:** Plastic insert for centrifuge tube**Classification name:** Assisted reproduction labware (21 CFR, 884.6160, Product code: MQK)**Indications for use:**

ProInsert™ is used during preparation of human sperm from a semen sample using density gradient separation during assisted reproductive procedures. ProInsert™ facilitates density gradient preparation and pellet retrieval following density gradient separation.

Description:

ProInsert™ is packaged in a sterile pouch, is single-use only, and includes the following components:
Two 15 mL Conical Centrifuge tubes (one for the density gradient preparation and one for washing)
2 Pellet Retrieval Pipettes
1 ProInsert™

**Device function/Scientific Concept**

Density gradient separation of sperm is performed to separate sperm from unwanted contaminants (e.g., abnormal or immature sperm, lymphocytes, cell debris, etc.). Generally, this involves layering semen over two layers of separation media of different density, followed by centrifugation to obtain a sperm pellet that leaves unwanted contaminants in the separation media above. Currently, to retrieve the pellet, a user must pass a retrieval pipette through the upper layers of the gradient or remove the gradient above the pellet. The ProInsert™ aids in recovery of the sperm pellet as it resides within the separation tube throughout the separation procedure. Following sperm pelleting, the sperm pellet can be retrieved by passing the Pellet Retrieval Pipette through the insert channel that avoids contact with gradient separation media above the pellet.

Device specifications:

Shelf life: 1 year

Endotoxin level: less than 1.0 EU/device.

Sterility: Gamma irradiated - SAL 10^{-6}

Human Sperm Survival Assay (HSSA): Greater than 80% motility following 24h exposure to device materials

Products claimed for substantial equivalence:

Substantial equivalence is being supported by the Federal Register Notice Final Rule entitled "Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures" (FR 63(175):48428-37). This equivalence is supported by the summary statement:

Upon the effective date, the Federal Register document may be cited in the absence of an existing predicate device which would be used to support substantial equivalence.

Fifteen milliliter centrifuge tubes historically have been a common piece of labware used in sperm gradient separation procedures. The proposed device differs from currently available 15 ml centrifuge tubes in that it includes an insert that facilitates gradient loading and recovery of the sperm pellet after completion of the procedure.

Performance testing: functionality testing

The ProInsert™ was tested with the following tests:

- Functionality testing gradient separation effectiveness using the ProInsert as compared to conventional separation procedures
- Endotoxin testing
- Sterility Validation.
- Shelf Life Testing
- Package Integrity Testing
- Material Safety Testing – HSSA

Lot Release Tests:

For the release of each production batch of this product, visual, performance, sterility, endotoxin analysis, and HSSA (human sperm survival) testing is done.

Conclusion

The testing performed demonstrates that this product meets design and testing requirements for assisted reproductive labware provided in 21 CFR 884.6160.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

NidaCon International AB
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, FL 34114

Re: K131145
Trade/Device Name: ProInsert™
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: January 16, 2014
Received: January 22, 2014

Dear Daniel 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131145

Device Name
ProInsert™

Indications for Use (Describe)

ProInsert™ is used during preparation of human sperm from a semen sample using density gradient separation during assisted reproductive procedures. ProInsert™ facilitates density gradient preparation and pellet retrieval following density gradient separation.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY:

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Herbert P. Lerner -S

2014.02.20 14:33:43 -05'00'