JUN 10 2014

510(k) Summary

This 510(k) Summary is provided per the requirements of section 807.92(c).

Date: April 11, 2014

Submitter Information:

Submitters Name:	Insightra Medical Inc.
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Device Name:

Trade Name:	Freedom Inguinal Hernia Implant
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Polymeric Mesh
Classification Code:	Class II, § 878.3300, Product Code FTL

Predicate Devices:

- Freedom Inguinal Hernia Implant, K113552, FDA cleared on 8/23/2012
- Ethicon Prolene Hernia System, K984220, FDA cleared on 2/23/1999
- Bard Perfix Plug, K922916, FDA cleared on 8/24/1992

Device Description:

The Freedom Inguinal Hernia Implant is used to plug or patch a hernia opening. The entire implant is made from polypropylene. It is comprised of two polypropylene meshes and two small polypropylene rings. A multi

looped shaped core fills the hernia opening while an underlay patch reinforces the defect and holds the implant in place. This underlay patch helps to prevent expulsion and rotation. Once the tissue defect is prepared, the implant is deployed into the defect area using the Delivery Device provided in the Freedom Inguinal Hernia Repair Kit. The Delivery Device serves to compact the implant and provide access to the defect opening to aid implantation. Once deployed, the tissue contracts around the implant, gripping it in place. Currently, the implants come in two different sizes; 25mm and 40mm with corresponding Delivery Devices to accommodate different size defects. The implant and delivery device are provided sterile for single patient use.

Intended Use:

The Freedom Inguinal Hernia Implant is intended to be implanted to reinforce soft tissues where weakness for open repair of inguinal hernias exist. No changes to the intended use have been made in this submission.

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The proposed modification to the device is a line extension to offer an additional 40mm size of the Freedom Inguinal Hernia Implant with a larger or extended underlay patch. The dimensions of the implant core remains identical to the current 40mm implant. The proposed extended 40mm implant underlay patch is identical to the predicate device previously cleared via K113552 in terms of its performance characteristics and has the same indications for use. Also, it has the same maximal dimension to the predicate device cleared via K984220.

The proposed Extended 40mm Implant Disk will differ in that the disk is ovoid in shape (egg shaped) from the current 40mm implant which is a small circle. This will accommodate surgeons who are accustomed to larger diameter underlay patches. Additionally, there is often weakened muscle/tissue structure adjacent to a repair that can benefit from mesh support to prevent a future hernia occurrence. The ovoid shape is similar

to the preperitoneal mesh disk of the predicate device cleared via K98422. However, it is smaller in all axes except for the maximal axis, where it is identical to K98422. This dimensioning is beneficial in that excess mesh is not used all the way around the area treated but only where needed.

The Delivery Device accessory included with the proposed Extended Disk remains the same and has the same intended use when used to deploy the implant as the predicate device cleared via K113552.

Performance Data:

Biocompatibility testing previously conducted (as presented via K113552) is also applicable to the proposed device and thus will not be repeated. All testing conducted to date (as per the requirements of ISO 10993) indicate that the device is biocompatible as per its intended use.

Bench testing results and in vivo simulated use experiments demonstrate that the proposed device design meets product specifications and intended use. In support of this submission, whole system simulated use testing was conducted in hernia simulators and fresh bovine meat to ensure that the proposed Freedom Inguinal Hernia Implant with Extended Disk met key user needs.

All test results provided in this submission support the safety and effectiveness of the device for its intended use and demonstrate that the proposed device is substantially equivalent to its predicate.

Conclusions Drawn from Nonclinical Tests:

The results of testing demonstrate that the Freedom Inguinal Hernia Implant with Extended Disk is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 10, 2014

Insightra Medical Incorporated
Ms. Lisa Maloney
Senior Regulatory Affairs Specialist
9200 Irvine Center Drive, Suite 200
Irvine, California 92618

Re: K140967
Trade/Device Name: Freedom Inguinal Hernia Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 14, 2014
Received: May 15, 2014

Dear Ms. Maloney:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Freedom Inguinal Hernia Implant

Indications for Use: The Freedom Inguinal Hernia Implant is intended to be implanted to reinforce soft tissues where weakness for open repair of inguinal hernias exist.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S