K113552

1 of 7

5 510(k) Summary

AUG 2 3 2012

a. Submitter

Applicant Name: Insightra Medical
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Contact Person: Wayne Noda

Date Summary Prepare: Revised August 22, 2012

b. Device Information

Trade Name: Freedom Inguinal Hernia Implant
Common Name: Surgical mesh
Classification Name: Surgical polymeric mesh (21 CFR 878.3300)
Product Code: FTL

c. Predicate Devices

Bard Perfix Plug (K922916)
Ethicon Prolene Hernia System (K984220)

d. Device Description

The Freedom Inguinal Hernia Implant is used to plug or patch a hernia opening. The implant is wholly manufactured 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. There are two different sizes of implants and corresponding delivery devices to accommodate different size defects. The implant and delivery device are provided sterile for single patient use.

e. Indications for Use:

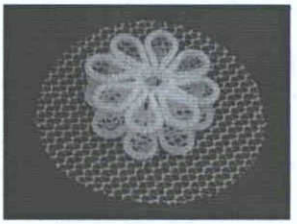
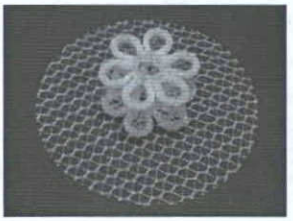
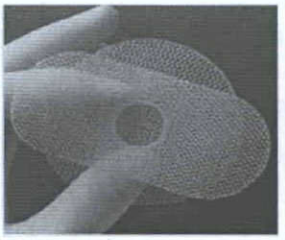
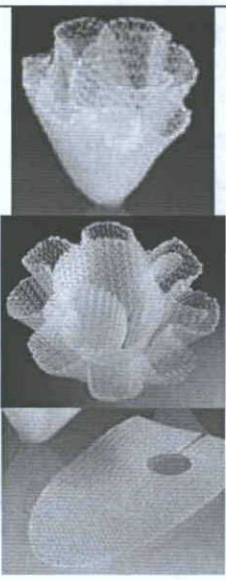
The Freedom Inguinal Hernia Implant is intended to be implanted to reinforce soft tissues where weakness for open repair of inguinal hernias exists.

f. Technological Characteristics and Comparison to Predicate Devices

The Freedom Inguinal Hernia Implant is of similar design and materials commonly used in other marketed hernia repair meshes.

Table 1 provides a comparison of the Freedom Inguinal Hernia Implant with the predicate hernia repair implants. This table illustrates the substantial equivalence of the subject device with the predicates.

Table 1 – Comparison Table for Freedom Inguinal Hernia Implant

	Freedom Inguinal Hernia Implant	Ethicon Prolene Hernia System	Bard Perfix Plug
510(k) Clearance	This submission	K984220	K922916
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 exists.	The PROLENE Hernia System is indicated for the repair of abdominal wall hernia defects	This product is indicated for the repair of groin hernia defects
Shape	 	 	
Texture	Mesh	Mesh	Mesh
Material	Polypropylene	Polypropylene	Polypropylene
Configuration	Underlay mesh patch, looped shaped mesh core	Underlay mesh patch, cylindrical mesh core, Onlay mesh patch	Conical multi layer mesh core, Onlay mesh patch
How is the implant secured?	Inserted into the hernia; no sutures necessary	Inserted into the hernia; no sutures necessary	Inserted into the hernia; no sutures necessary
Number of models	2	6	4
Size range (smallest to largest)	25 mm core & 60 mm dia. underlay patch 40 mm core & 70 mm dia. Underlay patch	Onlay patch – 44mm x 100mm to 55mm x 125mm Core Connector (for all sizes) – 19mm dia x 13mm height Underlay patch-75mm to 100mm diameter	25 x 34 mm to 41 x 50 mm; preshaped onlay patch same for all size plugs
Sterilization	EtO	EtO	EtO

g. Pre-Clinical Test Results:

In vitro, in vivo and biocompatibility tests were performed on the Freedom Inguinal Hernia Implant. The *in vitro* tests showed that the device meets pre-determined acceptance criteria or specifications that were based on the clinical demands placed on the device. The *in vivo* testing validated the implantation procedure and a survival study was performed that demonstrated the tissue incorporation of the implant. Results of the *in vivo* study were published in the journal of Artificial Organ (3). The biocompatibility testing showed the Freedom Inguinal Hernia Implant complies with the requirements for this device classification.

Cadaver studies were performed during the development of both the Freedom Inguinal Hernia Implant as well as the delivery device. These studies showed that the implant could be successfully deployed in the proper location and further validated the implantation technique. These results were considered in the final design configurations.

h. Results of Clinical Experience:

Two groups of data from relevant clinical experience were collected and reviewed. The first group of patients (n=61) received custom implants that were fabricated from surgical polypropylene mesh by the implanting surgeon. This was a single center, single surgeon clinical experience. In these patients, the surgeon used both stainless steel and rigid plastic tubes to provide the slight dilation of the defect and access required to deliver the implant. Patients were followed for a minimum of 3 years after the date of implantation. One patient was lost to follow up due to unrelated heart failure death after 14 months. The results demonstrated that defect dilation with tubes and treatment with flower shaped implants was safe and effective for the treatment of inguinal hernias. After 3 years, there have been no reports of unresolved post operative complications, recurrences, or chronic discomfort in these patients. The diameters of the dilation tubes were the same the diameters of the Insightra Medical Delivery Device, that is subject of this premarket notification.

The second group of patients reviewed (n=30) received the Insightra manufactured implant that is the subject of this submission. The implant was delivered using standard open surgical techniques using a previous version of the Freedom Inguinal Hernia Delivery System. This delivery system was identical dimensionally to the delivery system that is included in this premarket notification. Follow-up ranged from perioperative to one year post-implantation. Of these 30 patients, 27 were followed for a year or more with a mean followup of 25 months (ranging 11 to 36 months). There were no reports of unresolved perioperative complications, tissue injury or spermatic cord complications associated with this device.

In exceptional cases, an additional flat polypropylene mesh has been deployed to cover the inguinal floor, over the Freedom Inguinal implant that obliterates the hernia opening. This further reinforces the inguinal canal at the hernial protrusion when the groin structures appear obviously weak. The onlay flat mesh is not sutured or fixed to the inguinal structures, instead only connected to the central core of the Freedom Inguinal implant with a single polypropylene suture. Previous experiences of using this procedural variant produced, with the exception of some very seldom reported discomfort during the early postoperative stage, no unusual symptoms reported by patients who received the onlay patch in addition to the Freedom Inguinal implant.

For all patients in both groups reviewed with at least one year followup (n= 78) who received this dilation delivery technique, there were no reports of tissue tearing injury or spermatic cord injury. There have been no reports of dislodgements, unresolved post operative complications, chronic discomfort or recurrence of hernia. For the twenty seven patients in the second group who were followed for a year or more and received the Insightra Medical manufactured implant, there were no reports of spermatic cord injury or compression complications due to device rotation or inappropriate sizing.

The second study group by Amato (n=30) is summarized along with a third independent investigator sponsored study by Petrella, in the device labeling. Descriptive tables are included in the device "Technique Guide" as follows;

These clinical studies followed cohorts of patients (total n=54) that met the following inclusion/exclusion criteria:

Inclusion Criteria:	Exclusion Criteria:
• Scheduled to undergo routine inguinal hernia repair • Competent to give consent • Clinically relevant inguinal hernia (classification: NYHUS I, II, IIIa, IIIb) • Male or female • Over 18 years old to 85 years old • Life expectancy of at least 12-months • Diagnosed with direct, indirect or mixed inguinal hernia, unilateral or bilateral • Primary or recurrent hernia	• Signs of obvious local or systemic infection • Hernia was not in the inguinal area • Presenting with unstable angina or NYHA class of IV • Pregnant • Active drug user • Immunosuppression, prednisone>15 mg/day, active chemotherapy • End stage renal disease • Abdominal ascites • Skin infection in area of surgical field • BMI > 35

Both studies used the following objectives:

Primary Efficacy Objectives	Secondary Complications Objectives
• Procedural success is defined as the ability to successfully deploy the implant into the inguinal hernia defect • Freedom from hernia recurrence at the time points of 1, 6, 12, 24, 36 months	• Collection of data on any perioperative/postoperative complications (1, 6, 12, 24, 36 months) • Bleeding, swelling or hematoma from hernia defect dilation or improper delivery or implantation technique • Seroma, infection/abscess, testicular or spermatic cord injury in males, wound complications, symptomatic pain or chronic pain syndrome.

Amato Study	**Prospective study of a single operator case series of a modified plug technique and new 3D hernia implant**
Number of centers/investigators	1 center/ 1 investigators
Study Enrollment Period	June 2009 to August 2011
Number of patients	30
Number of implants*	25mm: n=12 40mm: n=22 *Four cases were double unilateral hernias
Patient demographics	Male = 30/Female = 0 BMI (Kg/m2) = 28.4 (21,7 – 34,9) Age = 50.23 mean, range 23-82 Hernia types: Indirect=17, Direct=13 Hernia size: Mean 32 mm (range 20 – 37,7) Hernia type: NYHUS Type 1 = 5 NYHUS Type 2 = 13 NYHUS Type 3a = 12 NYHUS Type 3b = 4
Operative procedure specifics	Anesthesia: Local = 63% Spinal = 17% General = 20% Procedure duration: Mean 29 minutes (range 22 – 38) Defect measurement: Intra operative measurement of the dissected flaccid defect using surgical scale for implant sizing
Patient Follow up Outcomes/adverse events	Follow up: Mean = 25.23 months (range 11.0-36.5) Outcomes/Adverse: no long term complications or recurrences at this time
Additional Outcomes – Two patients in this cohort received onlay mesh patches	In two exceptional cases, an additional flat polypropylene mesh was deployed to cover the inguinal floor, over the Freedom Inguinal implant that obliterated the hernia opening. This further reinforced the inguinal canal at the hernial protrusion when the groin structures appeared obviously weak. Patient #1 – Male, 82 yrs, Double unilateral hernia – Rt Indirect, Rt Direct, 25mm and 40mm implants used, Nyhus 2 & 3a. BMI: 29. Comorbidities: Myocardial ischemic disease, hypertension. Non recurrent hernias. Follow up = 18.2 mos. Patient #2 – Male, 75 yrs, Lf Mixed hernia, 40mm implant, Nyhus 3b. BMI: 26. Comorbidities: BPCO, myocardial insufficiency, hypertension. Non recurrent hernia. Follow up = 18.2 Results of these two procedures to date have had no complications or unusual symptoms. Patient #1 reported occasional discomfort

	during the early postoperative stage but self resolved after 5 months post op.
Ultrasound findings in cohort of patients	Full and stable obliteration of twelve patients examined at 3, 6 and 12 months.

Petrella/Venditti Study	**Prospective single arm study of the ProFlor Inguinal hernia Device**
Number of centers/investigators	1 center/ 2 investigators
Study Enrollment Period	Dec 2011 to present
Number of patients	24 enrolled; Target enrollment = 80
Number of implants	25mm: n=5 40mm: n=19
Patient demographics	Male = 22/Female = 2 BMI (Kg/m^2) = 25.2 (19,4 – 35,2) Age = 52.3 mean, range (31 – 73) Hernia types: Indirect=20, Direct=4 Hernia size: 15mm<Hernia size>40mm NYHUS Type 2 = 20 NYHUS Type 3a = 4
Operative procedure specifics	Local anesthesia Procedure duration: 24 min mean, (20-30) Defect measurement: Intra operative measurement of the dissected flaccid defect using surgical scale for implant sizing
Patient Follow up Outcomes/adverse events	Follow up: Mean = 4.5 months (range 3.0-6.0) Outcomes/Adverse: None observed
Ultrasound findings in cohort of patients	Ultrasound scans were not a requirement of the study and were not performed for this cohort

i. 510(k) Summary Conclusion:

In summary, the Insightra Freedom Inguinal Hernia Implant path through the 510(k) regulatory analysis is as follows:

- The Insightra Freedom Inguinal Hernia Implant and the Bard Perfix Plug and Ethicon Prolene Hernia System predicate devices, are all intended for use in the repair of inguinal hernia defects.
- The Insightra Freedom Inguinal Hernia Implant has similar key technological characteristics as the Bard Perfix Plug and Ethicon Prolene Hernia System devices. All three are manufactured from polypropylene mesh, all use mesh patch reinforcements, and all are inserted into the hernia defect without the need for suture;
- Although the Insightra Freedom Inguinal Hernia Implant and predicate devices have a minor technological difference in terms of the method of delivery, this difference does not raise any new types of safety or effectiveness questions. In addition, valid scientific methods exist for assessing the effects of the differences in delivery methods. Preclinical and clinical data demonstrate that these devices are substantially equivalent.

Therefore, the Insightra Freedom Inguinal Hernia Implant meets the criteria for substantial equivalence to the Bard Perfix Plug and Ethicon Prolene Hernia System predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 23 2012

Re: K113552
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: August 20, 2012
Received: August 21, 2012

Dear Mr. Noda:

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/ucm115809.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,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (K113552):

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 exists.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113552