Coloplast

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510(K) SUMMARY

510(k) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
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Name of Contact Person:	Janell Colley Regulatory Affairs Manager
Date Prepared:	November 2, 2012
Trade or Proprietary Name:	Altis® Single Incision Sling System
Common or Usual Name:	Surgical mesh
Classification Name/ Number/Product code:	Mesh, surgical, gynecologic, for stress urinary incontinence, female, single-incision mini-sling/ 21 CFR 878.3300/PAH

Legally Marketed Device To Which Your Firm Is Claiming Equivalence:

The Coloplast Altis Single Incision Sling System (hereafter referred to as the Altis System) is substantially equivalent in performance, indications, design and materials to Coloplast's Aris System (previously Mentor's), cleared under premarket notification K050148 on March 9, 2005, American Medical System's MiniArc System, cleared under premarket notification K073703 on January 30, 2008 and C.R. Bard Ajust Adjustable Single Incision Sling, cleared under premarket notification K092607 on November 20, 2009.

Device Description:

The Altis System is a single-incision mini-sling.. The sling material is manufactured using the commercialized Aris polypropylene mesh (K050148). Altis sling is made of a 0.08mm (nominal) diameter monofilament polypropylene mesh, knitted into a sling 1.1 cm wide by 7.75 cm long. One end of the sling assembly connects to a short length of USP size 1 monofilament polypropylene suture and to a polypropylene static (non-tensioning) anchor. The second side of the sling assembly terminates to a longer section of USP size 1 monofilament polypropylene suture. This suture is then positioned through the second anchor that is dynamic with an integrated tensioning system. The tensioning capability is accomplished by threading the suture through a polyurethane tensioning collar which is assembled onto the anchor. The anchor/suture assembly wraps around the anchor, resulting in a gap between the anchor and the collar providing constant pressure on the suture, preventing it from moving on its own, or during a pelvic stress event. Tensioning is achieved by pulling on the suture loop, thus applying increased tension of the sling to the urethra until desired support is achieved. The Altis anchors perform an acute mechanical role of maintaining the desired position and tension through the acute post-operative tissue healing and in-growth phase, The Altis sling assembly is packaged with two (2) helical type introducers (one right, one left) that are used to place the sub-urethral sling. The Altis introducers are designed with the appropriate curvature and length to allow the physician to reach

the obturator foramen through a single vaginal incision. The tip of the needle is designed to fit into the anchors to facilitate placement into the obturator foramen during the surgical implant procedure. The sling assembly pouch and introducers are placed in a tray sealed with a Tyvek lid. The Altis system (implant plus introducers) is provided sterile (ethylene oxide) and is for single use only.

Intended Use Of The Device:

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Technological Characteristics Compared To Predicate Device:

The Altis System is substantially equivalent in design, materials, performance characteristics, and indications to the predicates; Coloplast (formerly Mentor) Aris Mesh, cleared under premarket notification K050148 on 9 March 2005, American Medical System's MiniArc System, cleared under premarket notification K073703 on 30 January 2008 and C.R. Bard Ajust Adjustable Single Incision Sling, cleared under premarket notification K092607 on November 20, 2009.

The Altis, Aris, Ajust, and MiniArc Systems have the same intended use, mesh material (i.e., knitted polypropylene monofilament), introducer instrument for implantation provided with implant, sterilization method (i.e., ethylene oxide), and transobturator surgical approach. The Altis and Aris Systems use identical mesh material and introducer materials. The Altis, Ajust, and MiniArc Systems utilize polypropylene anchors and a single incision technique. The Altis and Ajust Systems have the following similarities: Altis and Ajust may be tensioned intraoperatively via a tensioning system connected to a tissue anchor; Altis and Ajust utilize helical type introducers which control positioning and placement of tissue anchors in the obturator space while avoiding the vascular and nerve bundles.

While the predicate Aris sling utilizes multiple incisions, the Altis, Ajust, and MiniArc systems use a single-incision surgical technique. The Altis and Ajust introducer radii are smaller than the Aris introducer radius, consistent with the difference in surgical approach. In terms of tensioning, the predicates have the following differences:

- Aris is a full length sling that is placed using a relatively tension-free method
- MiniArc is tensioned by pushing the anchors deeper into tissue; no further increase in tensioning is possible after introducers needles are removed and tension on the sling cannot be loosened if anchors are placed too deeply
- Ajust utilizes a tubular piece of mesh (attached to the sling) moving through its anchor to position the mesh beneath the urethra. When the physician has positioned the Ajust sling, a plug pre-positioned in the mesh tube is advanced using a stylet that is inserted to push the plug up the tube to limit the anchor mobilization.
- Altis utilizes suture attached to the sling that moves through the anchor in order to position the mesh beneath the urethra. When the physician has positioned the Altis sling, the tensioning system relies on compression force applied by the anchor/suture assembly to allow for precise positioning

Summary from the Nonclinical Tests Submitted:
Design verification (bench) testing was conduct on the Altis mesh and introducers and included the all recommended evaluations detailed in FDA's Guidance for Preparation of a Premarket Notification Application for a Surgical Mesh, including mesh thickness, mesh weave characteristics, pore size, mesh density, tensile strength, device stiffness, suture pullout strength, burst strength, tear resistance, device thickness, pore size, and burst strength. In addition, introducers were tested for pull out forces of needle from handle, torsion resistance of needle from handle, and handle diameter.

All testing results demonstrated acceptable results based on the established specifications.

Biocompatibility testing per ISO 10993 and per FDA's Guidance for Preparation of a Premarket Notification Application for a Surgical Mesh was conducted on the Altis mesh and introducers, including cytotoxicity, sensitization, irritation, systemic toxicity (acute), genotoxicity, implantation (with histology of the surrounding tissue, hemolysis, pyrogenicity, heavy metals residuals, pyrogen levels

All biocompatibility testing results demonstrated acceptable results based on the established specifications.

Simulated use evaluations were conducted in animals and human cadaveric laboratory testing per FDA Design Control requirements. All testing results demonstrated acceptable results based on the established specifications.

Summary from the Clinical Tests Submitted:
The clinical study of the Altis Sling System was a prospective, single arm, non-randomized, multi-center trial conducted at 17 sites in the US and Canada. The objective of the study was to assess safety and efficacy of the Altis single incision sling system for females with SUI. A total of 113 women were implanted with the Altis Sling. The median age for the women enrolled in the study was 54.5 years (range = 25.3 – 89.3). The median body mass index (BMI) was 29.9 (range = 20.0-55.8).

The study's primary effectiveness objective was improvement in subject continence status measured by reduction in 24-hour pad weight. At 6 months, 88 of 103 evaluable subjects showed >50% reduction in pad weight compared to baseline.

Secondary effectiveness endpoints included cough stress test (CST) at 6 months, assessment of subject Quality of Life (QOL) through validated questionnaires at 6 months, and voiding diaries were evaluated using performance goals. All results were statistically significant.

Results of CST, UDI-6, IIQ-7, and Voiding Diary

Endpoint	Success	Lower 95.81% CL	p-value
Cough Stress Test[1]	92.2% (95/103)	86.1%	<0.0001
UDI Score[2]	88.6% (93/105)	81.8%	<0.0001
IIQ Score[3]	93.3% (97/104)	87.4%	<0.0001
Voiding Diary[4]	88.0% (81/92)	80.6%	<0.0001

[1]Percent of subjects with negative cough stress test at 6 months
[2]Percent of subjects with ≥ 50% reduction in UDI Score at 6 months
[3]Percent of subjects with ≥ 50% reduction in IIQ Score at 6 months
[4]Percent of subjects with ≥ 50% reduction in number of incontinence episodes at 6 months

Device related events included 4 mesh extrusions (3.5%) and one case (0.9%) each of dypareunia, retention, UTI, inflammation, worsening OAB, and decreased urine stream. There were two device and/or procedure related serious adverse events: hematoma requiring hospitalization following a second sling revision due to urinary outlet obstruction, and a vaginal mesh extrusion for which explant surgery was indicated.

Conclusions

The Altis Sling system is substantially equivalent to its legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: November 5, 2012

Coloplast A/S
% Ms. Janell A. Colley
Regulatory Affairs Manager
1601 West River Road North
MINNEAPOLIS MN 55411

Re: K121562
Trade/Device Name: Altis® Single Incision Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: October 25, 2012
Received: October 26, 2012

Dear Ms. Colley:

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,

Herbert P. Lerner

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): K121562

Device Name:

Altis Single Incision Sling System

Indications for Use:

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Prescription Use ___X__ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (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)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121562