Section 5 – 510(k) Summary

1) SUBMITTER

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2) DEVICE

Name of Device : Rigi10™ Malleable Penile Prosthesis
Common or Usual Name : Penile Prosthesis
Classification Name : Penile Rigidity Implant
Regulatory Class : Class II
Regulation : 21 CFR 876.3630
Product Code : FAE

3) PREDICATE DEVICE

Coloplast (formerly Mentor Corp.) Genesis Penile Prosthesis, K040959
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4) REASON FOR 510(K) SUBMISSION

Rigi10 Malleable Penile Prosthesis is a new model.

5) DEVICE DESCRIPTION

Rigi10 malleable penile prosthesis is a sterile, non-pyrogenic, single–use surgical implant.

The device core consists of a malleable stainless-steel core, with titanium caps on both ends, and a PTFE (Polytetrafluoroethylene) tube cover. The entire outside surface of the cylinder is made out of silicone. The malleable stainless-steel core enables the prosthesis to be moved into an erect position when desired and also enables the concealment of the

prosthesis under clothing. All components consist of implantable, biocompatible materials.

The device consists of two cylinders, and extenders. The cylinders are surgically implanted, one into each corpus cavernosum, to provide penile rigidity.

The prosthesis comes in two lengths. This includes 23 cm and 25 cm. The length is determined by the diameter of the prosthesis. Rigi10 Malleable Penile Prosthesis is available in five different diameter sizes; 9 mm, 10 mm, 11 mm, 12 mm, and 13 mm. Cylinders with 9 mm and 10 mm diameters are available in 23 cm length while cylinders with 11mm, 12 mm and 13 mm diameters are available in 25 cm length. There are four extenders (two pieces of 0.5 cm and two pieces of 1.0 cm) included in each product package. The extenders are accessories of the device and are available for adjusting the length of the prosthesis to match the total corporal measurement of the patient.

Patients diagnosed with erectile dysfunction are candidates for Rigi10 Malleable Penile Prosthesis implantation. The device should only be implanted by specialized physicians (e.g. urologists and surgeons)

6) INDICATIONS FOR USE

The malleable penile prosthesis is indicated for implantation into the corpora cavernosa of the penis in men who are diagnosed with erectile dysfunction. The prosthesis is implanted to provide adequate penile rigidity for sexual intercourse.
The prosthesis is designed for the treatment of organic erectile dysfunction in men due to:

- Pelvic fracture,
- Spinal cord injury or disease,
- Prostatectomy,
- Multiple sclerosis,
- Diabetes mellitus,
- Arteriosclerosis,
- Hypertensive vascular disease,
- Priapism,
- Peyronie’s disease,
- Selectively for psychogenic impotence.

The Indications for Use statement for the Rigi10 Malleable Penile Prosthesis is not identical to the predicate device (i.e. K040959) however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and

effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the treatment of erectile dysfunction, by providing adequate penile rigidity for sexual intercourse.

7) SUBSTANTIAL EQUIVALENCE CLAIM

Rigi10 Malleable Penile Prosthesis is substantially equivalent to the predicate device (i.e. Coloplast (formerly Mentor Corp.) Genesis Penile Prosthesis) The devices have same intended use, indications for use and target population. The devices are mainly manufactured with similar material (i.e. silicone elastomer) with minor differences such as stainless-steel core and PTFE cover in Rigi10 while the predicate device has a silver core and a polyester cover. Subject and predicate devices are sterilized with the same sterilization methods (i.e. EtO sterilization).

Testing rationale was provided to support the equivalence of the Rigi10 Malleable Penile Prosthesis and shows that no new concerns of safety and effectiveness have been introduced with this device.

The safety and effectiveness of the Rigi10 Malleable Penile Prosthesis are adequately supported by the testing rationale, substantial equivalence information, materials information, and comparison of design characteristics provided with the submission document.

Because the intended use and the fundamental scientific technology of the predicate device are similar with the subject device a clinical study was not conducted for Rigi10 Malleable Penile Prosthesis.

8) PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility tests:

- In Vitro Cytotoxicity Test
- Skin Sensitization Test
- Intracutaneous Reactivity Test
- Acute Systemic Toxicity Test
- Pyrogen Test
- Bacterial Endotoxin Test
- Implantation Tests
- Chemical Characterization Test
- Toxicological Risk Assessment
- Rabbit Blood Hemolysis Test

The device met all biocompatibility test specifications. The tests were carried out in accordance with the ISO 10993-1 “Biological evaluation of medical devices” guideline.

Bench performance tests:

- Simulated Life/Fatigue Testing,
- Positioning/Concealability Testing,
- Buckling Testing,
- Tip Extender Joint Strength Testing.

Sterilization by ethylene oxide has been validated for Rigi10 Malleable Penile Prosthesis.

For each bench performance test, an acceptance criterion was established prior to testing and the outcome of each test was that the acceptance criteria would be met to demonstrate statistically significant substantial equivalence to the predicate device.

The device met all performance test specifications and passed all tests.

9) CONCLUSION

Biocompatibility evaluation for Rigi10 malleable penile prosthesis was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. These tests confirm that Rigi10 malleable penile prosthesis is as safe as the predicate device.

Bench test evaluations for Rigi10 malleable penile prosthesis was conducted in accordance with the “Guidance for the Content of Premarket Notifications for Penile Rigidity Implants” January 16, 2000. These tests confirm that Rigi10 malleable penile prosthesis is as safe and effective as the predicate device.

The performance data support the safety of Rigi10 malleable penile prosthesis and demonstrate that Rigi10 is as safe, as effective, and performs as well as the legally marketed device predicate (i.e. Coloplast (formerly Mentor Corp.) Genesis Penile Prosthesis, K040959) that is currently marketed for the same intended use.