Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
508-683-4000
www.bostonscientific.com

510(k) Summary

Submitter

Boston Scientific Corporation
10700 Bren Road West
Minnetonka, MN 55343
USA

Phone: 952-930-6252

Contact Person: Laura Kelly
Date Prepared: December 21, 2018

Device:

Name of Device: Tactra™ Penile Prosthesis
Common or Usual Name: Malleable Penile Prosthesis
Classification Name: Penile Rigidity Implant (per 21 CFR 876.3630)
Regulatory Class: II (Special Controls)
Product Code: FAE

Predicate Device

AMS Spectra™ Concealable Penile Prosthesis (K090663)
Mentor (Coloplast) Genesis™ (K040959)

No reference devices were used for this submission.

Device Description

The Tactra Penile Prosthesis is a sterile, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in adult males who are determined to be suitable candidates for implantation surgery.

The Tactra Penile Prosthesis is a malleable implant which consists of a pair of cylinders which are surgically implanted, one into each corpus cavernosum, to provide penile rigidity for adult males with erectile dysfunction. The two cylinders are available in diameters of 9.5 mm, 11 mm, and 13 mm. The proximal end of each cylinder has an 8 cm trimmable zone for length adjustment as desired by the physician. The working length of each cylinder is the total length including the “0” cm Rear Tip Extenders (RTE). Since each cylinder has an 8 cm zone to be trimmed, the working length for each diameter cylinder encompasses the range shown in the table below. If additional length is needed, alternate RTEs (0.5 cm or 1 cm) can be attached to the proximal end of each cylinder prior to implantation.

All components consist of implantable, biocompatible materials and are provided as sterile, single-use implants. These implants may not be re-sterilized.

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
508-683-4000

www.bostonscientific.com

The Tactra Penile Prosthesis will be available in the following configurations:

Configuration	Outer Diameter	Working Length	RTE Offering
1	9.5 mm	14 – 23 cm	0 cm, +0.5 cm, +1 cm
2	11 mm	16 – 25 cm	0 cm, +0.5 cm, +1 cm
3	13 mm	18 – 27 cm	0 cm, +0.5 cm, +1 cm

Indications for Use

The Tactra™ device is designed to provide penile rigidity and malleability, and the device can be placed in either an erect or a concealed position.

The Tactra Penile Prosthesis is a sterile, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in adult males who are determined to be suitable candidates for implantation surgery.

Comparison of Technological Characteristics with the Predicate Device

The Tactra Penile Prosthesis incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices, AMS Spectra Concealable Penile Prosthesis (K090663) and the Mentor (Coloplast) Genesis (K040959).

Performance Data

To demonstrate substantial equivalence of the Tactra Penile Prosthesis to the predicate devices, technological characteristics and performance criteria were evaluated using bench testing, and biocompatibility testing.

The results from this testing demonstrate that the technological characteristics and performance criteria of the Tactra Penile Prosthesis do not raise new questions of safety and effectiveness in comparison to the predicate devices.

Conclusion

As the intended use and fundamental scientific technology have not changed, non-clinical data supports a determination that there are no new questions of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate devices, and that it is at least as safe and effective for its intended use.