DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K183619

Device Name

Tactra™ Penile Prosthesis

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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