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)*
K181673

Device Name
RIGI 10 MALLEABLE PENILE PROSTHESIS

Indications for Use *(Describe)*
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.

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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