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)*

K183398

Device Name

Endoform Restella

Indications for Use *(Describe)*

Endoform Restella is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

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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