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)*
K183613

Device Name
exGraft and exGraft Carbon ePTFE Vascular Grafts

Indications for Use *(Describe)*
The exGraft and exGraft Carbon ePTFE Vascular Grafts are indicated for use as vascular prostheses.

The exGraft and exGraft Carbon ePTFE Vascular Grafts are intended for use as subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of peripheral arterial blood vessels.

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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