K183613

510(k) Summary

(as required by 21 CFR 807.92)

I. SUBMITTER

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II. DEVICE

Name of Device:	exGraft and exGraft Carbon ePTFE Vascular Grafts
Common or Usual Name:	Vascular Graft
Classification Name:	21 CFR 870.3450 Prosthesis, Vascular Graft
Regulatory Class:	Class II
Product Code:	DSY

III. PREDICATE DEVICE

exGraft and exGraft Carbon ePTFE Vascular Grafts [K180957]. The predicate has not been subject to a design-related recall.

Impra ePTFE Vascular Grafts [K830543] and Impra Carboflo ePTFE Vascular Grafts [K004012 and K004011] were used as reference devices.

IV. DEVICE DESCRIPTION

The exGraft and exGraft Carbon ePTFE Vascular Grafts are single use sterile vascular grafts constructed of expanded polytetrafluoroethylene (ePTFE) with a radiopaque ink applied to the surface. The exGraft Carbon ePTFE vascular grafts also contain a carbon coating impregnated into the inner surface of the graft wall.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed exGraft and exGraft Carbon and the predicate device exGraft and exGraft Carbon ePTFE Vascular Grafts [K180957] have the following similarities:

- Same basic design and material
- Sterilized using the same material and processes
- Same packaging material and construction
- Carbon impregnated and non-carbon impregnated
- Radiopaque ink applied to the outer surface

The proposed exGraft and exGraft Carbon and the predicate device exGraft and exGraft Carbon ePTFE Vascular Grafts [K180957] have the following differences:

- Different available length and diameter configurations

The different available length and diameter configurations are considered technological differences but do not raise different questions of safety and effectiveness and can be evaluated with performance testing.

VII. PERFORMANCE DATA

The proposed exGraft and exGraft Carbon ePTFE Vascular Grafts leverage historical data from the predicate and reference devices.

In addition, the following testing was performed to support substantial equivalence to the predicate device.

- Kink Radius
- Microscopic Porosity (Upper and Lower Limit)
- Water Entry Pressure
- MRI Safety Evaluation

CONCLUSION

Compared to the predicate device, the exGraft and exGraft Carbon ePTFE Vascular Grafts has the same intended use and the technological differences do not raise different questions of safety and effectiveness. Based on historical data and performance testing, the exGraft and exGraft Carbon are substantially equivalent to the predicate device.