

JAN - 8 2001

K990800

### 510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Part 807.92.

Name: Robert Hill, Director Regulatory Affairs & Quality Assurance

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Trade Names: InterGard Knitted Collagen Coated & Heparin Bonded Vascular Prostheses.  
InterGard Knitted Ultra-Thin Collagen Coated & Heparin Bonded Vascular Prostheses.

Common Names: Vascular Prostheses or Grafts

Classification Name: 21 CFR 870.3460, Vascular graft prostheses of 6 mm and greater diameter

Predicate Names: InterGard Knitted Collagen Coated Vascular Prostheses  
InterGard Knitted Ultra-Thin Collagen Coated Vascular Prostheses

The InterGard Knitted Collagen Coated & Heparin Bonded Vascular Prostheses, including Knitted Ultra-Thin, are vascular grafts made of Dacron fabric and coated with bovine collagen crosslinked with glutaraldehyde. The prostheses are offered in numerous lengths and diameters exceeding 6 mm.

The InterGard Knitted Collagen Coated & Heparin Bonded Vascular Prosthesis is indicated for surgical repair, bypass or replacement of arteries in the treatment of aneurysmal and occlusive disease of the abdominal aorta, visceral arteries and peripheral arteries. Due to the low porosity of the InterGard vascular grafts, these products are recommended for use in patients requiring heparinization prior to or during surgery. The Indications for these products are the same as the predicate devices.

The InterGard Knitted Collagen Coated and Heparin Bonded Vascular Prostheses have similar technological characteristics as their predicate devices, including the use of the same underlying fabric and collagen coating material. These products also meet the same strength (circumferential probe burst and radial strength), collagen adherence, and water permeability

specifications as the predicate devices. Testing was conducted consistent with AAMI Standards for vascular prostheses. These results were validated by bench and animal studies and further supported by published clinical data.

Based on the conclusions drawn from the safety analysis conducted on this device, the InterGard Knitted Collagen Coated & Heparin Bonded vascular grafts are safe and perform in a manner equivalent to the predicate devices mentioned above.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN - 8 2001

Mr. Vincent Bucci  
President  
Health Policy Associates, Inc.  
c/o InterVascular, Inc.  
20 Walnut Street, Suite 12  
Wellesley, MA 02181

Re: K990800/S3  
Trade Name: InterGard Knitted Ultra Thin Collagen Coated and  
Heparin Bonded Vascular Prosthesis and InterGard  
Knitted Collagen Coated and Heparin Bonded Vascular  
Grafts  
Regulatory Class: II  
Product Code: DSY  
Dated: November 21, 2000  
Received: December 11, 2000

Dear Mr. Bucci:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

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concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



for James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**PRODUCT INDICATIONS FOR USE**  
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510(k) Number: K990800

Device Names: InterGard Knitted Collagen Coated and Heparin Bonded Vascular Prosthesis

InterGard Knitted Ultra Thin Collagen Coated and Heparin Bonded Vascular Prosthesis

Indications for Use: InterGard Collagen Coated and Heparin Bonded vascular prostheses are indicated for surgical repair, bypass, or replacement of arteries in the treatment of aneurysmal and occlusive disease of the abdominal aorta, visceral arteries, and peripheral arteries. Due to the low porosity of the grafts, these products are recommended for use in patients requiring heparinization prior to or during surgery.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

 1-5-01

Division of Cardiovascular & Respiratory Devices  
510(k) Number K990800