

## 510(k) Summary

(As required by 21 CFR 807.92(c))

510(k) Number: K073200

### Date Prepared

January 16, 2008

FEB -1 2008

### Submitter Information

Submitter's Name: Vascular Solutions, Inc.  
Address: 6464 Sycamore Court  
Minneapolis, MN 55369

Contact Person: Julie Tapper  
Senior Regulatory Affairs Associate  
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### Device Information

Trade Name: Gandras™ Intravascular Catheter  
Common Name: Diagnostic intravascular catheter  
Class: II  
Classification Name: Diagnostic intravascular catheter  
(21 CFR 870.1200, Product Code DQO)

### Predicate Devices

Renegade STC™ 18 Microcatheter (K023681, K020012), manufactured by Boston Scientific Corporation.

AngioDynamics Soft-Vu and AngioDynamics Mariner Hydrophilic Coated Catheters (K061733), manufactured by AngioDynamics, Inc.

### Device Description

The Gandras catheter is an angiographic intravascular catheter that has a working length of approximately 80cm, not including the tip length. The Gandras catheter is offered in three tip lengths—2cm (model 5580), 4cm (model 5581), or 6cm (model 5582). Each catheter assembly has a single lumen that is formed by a segment of nylon that extends distally from the hub, a segment of 40 durometer Pebax that extends distally from the nylon, and pellethane that forms the distal tip. Each catheter also has a Texin outer layer that overlays the nylon and pebax tubing in the mid-shaft. The distal 10-15cm of the catheter is hydrophilically coated to provide a lubricious outer surface. The catheter's radiopacity is provided by 40% bismuth subcarbonate loading in the nylon, 60% tungsten loading in the Pebax, and 65% tungsten loading in the pellethane tubing components.

Each catheter has a press-fit luer hub and strain relief on the proximal end, and a peelable tip straightener. Each Gandras catheter is compatible with  $\geq 5F$  introducer sheaths and  $\leq 0.035$ " guidewires.

The Gandras catheter is provided sterile and intended for a single use.

### **Intended Use/Indications for Use**

The Gandras catheter is designed to be used for delivering embolic materials and radiopaque media to selected sites in the vascular system. Diagnostic, embolic, or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

### **Summary of Non-clinical Testing**

Bench testing was conducted on the Gandras catheter, including the packaging, and included an assessment of the physical properties of the device and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use. Each bench test that was conducted is listed, below.

Hydrophilic coating lubricity	Dynamic pressure
Visual inspection	Liquid leak under pressure
Packaging stylet removal force	Static pressure
Corrosion resistance	Leak During Aspiration
Catheter Radiopacity	Kink resistance
Curve retention	Hub bond strength
Guidewire passage	Proximal to mid shaft strength
Introducer sheath passage	Mid to distal shaft strength
Tortuosity	Tip straightener peel test
Embolic material passage	Packaging—Product Visual Appearance after Distribution Testing
Flow rate with contrast	Packaging—Label Legibility after Distribution Testing

### **Summary of Clinical Testing**

Clinical evaluations were not required for this device.

### **Statement of Equivalence**

The Gandras catheter is substantially equivalent to the currently marketed Renegade STC, Soft Vu, and Mariner catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods.

### **Conclusion**

The Gandras catheter is substantially equivalent to the currently marketed Renegade STC, Soft Vu, and Mariner catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vascular Solutions, Inc.  
c/o Ms. Julie Tapper  
Senior Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, MN 55369

Re: K073200  
Trade Name: Gandras™ Intravascular Catheter  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II  
Product Code: DQO  
Dated: January 16, 2008  
Received: January 17, 2008

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

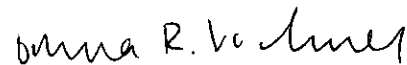
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: **K073200**

**Device Name:**

Gandras™ Intravascular Catheter

**Indications for Use:**

The Gandras catheter is designed to be used for delivering embolic materials and radiopaque media to selected sites in the vascular system. Diagnostic, embolic, or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –  
CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Beckney*  
(Division Sign-Off)  
Division of Cardiovascular Devices

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