

**10.0 SUMMARY OF SAFETY AND EFFECTIVENESS**

**Manufacturer:** IntraVascular Incorporated  
3600 Bur Wood Drive  
Waukegan, Illinois 60085

**Contact:** Steve Aperavich  
President, IntraVascular Incorporated

**Telephone Number:** 847-596-7700  
**Fax Number:** 847-596-7710

**Date Summary Prepared:** November 18, 2002

**Product Trade Name:** FLOSTAR Needleless Connector

**Common Name:** Needle-less I.V. Access Valve

**Classification:** Set, Administration, Intravascular  
21 CFR 880.5440

**Predicate Devices:** Safe-Connect Valve

**Description:**

The FLOSTAR Needleless Connector is a sterile, disposable, needle-less I.V. access valve for use in general intravenous administration of fluids.

**Intended Uses/Indications:**

The FLOSTAR Needleless Connector device is sterile, disposable, needle-less I.V. access valve for use in intravenous administration of fluids to a patient's vascular system. The FLOSTAR Needleless Connector device may aid in the prevention of needle stick injuries.

**Substantial Equivalence:**

The FLOSTAR Needleless Connector is substantially equivalent to the current Safe-Connect Valve in that:

- have the same intended use,
- use the same operating principle,
- incorporate the same final design configuration
- are both labeled as single patient use
- are packaged and labeled using the same materials and processes

IntraVascular Incorporated  
FLOSTAR Needleless Connector Special 510(k) Notification

**Summary of Testing:**

All materials used in the fabrication of this FLOSTAR Needleless Connector were evaluated with the original design through physical testing and biocompatibility testing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 21 2002

Mr. Steve Aperavich  
President  
IntraVascular Incorporated  
3600 Bur Wood Drive  
Waukegan, Illinois 60085

Re: K023585

Trade/Device Name: FLOSTAR Needleless Connector  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: FPA  
Dated: October 22, 2002  
Received: October 25, 2002

Dear Mr. Aperavich:

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.

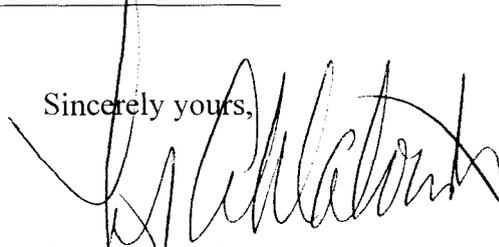
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

