JUL 1 2003

K031783

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: Fax Number:	847-596-7700 847-596-7710
Date Summary Prepared:	June 9, 2003
Product Trade Name: Common Name:	Safe Connect™ Drug Dispensing Spike Needle-less Access Spike Classification: Set, Administration, IntraVascular 21 CFR 880.5440
Predicate Devices:	Safe Connect™ Vial Dispensing Spike

Description:

The Safe-Connect™ Drug Dispensing Spike is a sterile, single use, needle-less access spike for use in general administration of fluids.

Intended Uses/Indications:

The Safe-Connect™ Drug Dispensing Spike is a sterile, single use, needle-less access spike for use in general administration of fluids and/or removal of drugs from standard drug containers. The Safe-Connect™ Drug Dispensing Spike may aid in the prevention of needle stick injuries.

Substantial Equivalence:

The Safe Connect™ Drug Dispensing Spike is substantially equivalent to the current Safe Connect™ Vial Dispensing Spike 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

Summary of Testing:

All materials used in the fabrication of this Drug Dispensing Spike were evaluated with the original and proposed designs through biocompatibility testing. The proposed devices will perform in an equivalent manner to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

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

Re: K031783
Trade/Device Name: Safe-Connect Drug Dispensing Spike
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 6, 2003
Received: June 10, 2003

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031783

Device Name: Safe-Connect™ Drug Dispensing Spike

Indications For Use:

The Safe-Connect™ Drug Dispensing Spike is a sterile, non-pyrogenic, single use device to be used in dispensing drugs from drug containers. The device is to be used by a trained healthcare professional using Aseptic Techniques for the addition of liquid diluents to powdered drug products for reconstitution, addition of liquids to concentrated liquid drugs for dilution, and/or the withdrawal of the reconstituted and liquid drug products from drug containers by the use of a standard luer tapered syringe. The device is indicated to allow for multiple accesses and withdrawals from the same drug container using standard hospital disinfectant solutions and procedures without the requirement of using a sterile cap to maintain fluid path integrity. The Safe-Connect™ Drug Dispensing Spike may aid in the prevention of needle stick injuries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K031783