



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 2004

Mr. William Reilly  
President  
IVY Devices, Incorporated  
P.O. Box 23241  
Grande Prairie, Alberta Canada  
T8V-6X2

Re: K033208  
Trade/Device Name: IVY Devices Incorporated IV/ Medical Line Stabilizer  
Regulation Number: 880.5440  
Regulation Name: Intravascular powdered Fluid Injector  
Regulatory Class: II  
Product Code: FPA  
Dated: January 12, 2004  
Received: January 20, 2004

Dear Mr. Reilly:

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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

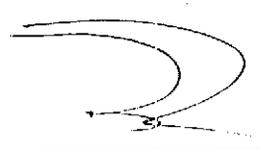
Enclosure

**STATEMENT OF INDICATIONS FOR USE**

510(k) Number: K033208

Device Name: **IVY Devices Inc. IV/Medical Line Stabilizer**

The IV/Medical Line Stabilizer is non-sterile, single use, identified in 21 CFR 880.5440, as a medical device intended to be used by personnel who are most often in contact with pediatric patients that have intravenous lines or medical lines attached to them. The IV/Medical Line Stabilizer is made of latex-free food grade transparent plastic. The primary purpose of this device is to reduce the risk of intravenous and other medical line entanglement. The design of the IV Stabilizer helps prevent IV wraps or medical line(s) from entangling around itself and around the patient.



William Reilly

September 26, 2003

Date

K033208

Pre-market Notification (510K Number)

*Gene Newman* Interim Branch Chief

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

510(k) Number: K033208

Prescription Use ✓