

K 983480

NOV 23 1998

510(k) Summary

BPOS-IVAD STABILIZER

1. DATE PREPARED
September, 1998

2. SPONSOR INFORMATION:

Address: Bob Burns, Terry Shaffer, Jean Perlick
#7 Coralwind
Aliso Viejo, CA 92656-1428

Contact Person: Ms. Terry Shaffer
Ph: (949) 455-9636
Fax: (949) 455-9636

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3. **DEVICE NAME:**

Grade/Proprietary Name: BPOS-IVAD STABILIZER

Common Usual Name: Implanted Vascular Access Device Stabilizer

Classification Name: Vein Stabilizer

CFR 880.6980

Product Code 80 LBJ E Class I

4. **DEVICE DESCRIPTION AND INTENDED USE:**

The BPOS-IVAD STABILIZER is a non-invasive two-pronged device used to stabilize an area of the skin over an implanted vascular access device while performing a procedure on that immediate area.

5. **PREDICATE DEVICE**

The BPOS-IVAD STABILIZER is similar in design, function and intended use to a vein stabilizer. The vein stabilizer is a non-invasive two-pronged device that stabilizes an area of skin while performing a procedure on that immediate area.

6. **DEVICE TESTING**

No testing has been done.

Both devices utilize a plastic platform to stabilize the area while a procedure is performed on the immediate area between the prongs. Both devices are made of plastic. Both devices use hand pressure to the device to guide and provide leverage to assist in the procedure performed between the prongs. The anatomical site (needle insertion site) target patient and use populations (HCW) are the same for each device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terry Shaffer, R.N.
Principal
BPOS, Incorporated
#7 Coralwind
Aliso Viejo, California 92656-1428

Re: K983480
Trade Name: BPOS-IVAD STABILIZER
Regulatory Class: Unclassified
Product Code: LJT
Dated: October 2, 1998
Received: October 2, 1998

Dear Ms. Shaffer:

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 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.

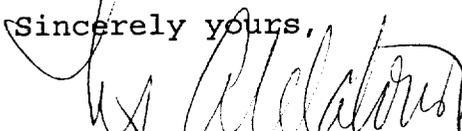
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 concerning your device in the Federal Register. Please note: this response to your pre-market 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.

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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), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director

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

Enclosure

510(k)

K983480

Device Name: BPOS-IVAD STABILIZER

Indications for Use:

The tool is intended for use in assisting to externally stabilize the area of skin over the site of an implanted vascular access device, while a needle, which is implanted into the device, is removed from the device, manually, without direct contact between the user's hands and the intravascular access device site.

Concurrence of CDRN, Office of Device Evaluation (ODE)

Prescription Use or
(Per 21 CNR 801.109)

Over-the-Counter Use

Patricia Cuente

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

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