

MAY 14 1998

*Summary of Safety and Effectiveness  
for AV Fistula Needle Protector (AVFNP)*

K991404

**Submitter**

ITL Corporation  
22 Molonglo Mall  
Fyshwick, 2609  
Canberra, Australia

**Date summary was prepared**

June 16, 1998

**Name(s) of the device**

AV Fistula Needle Protector (AVFNP)

**Identification of predicate device(s)**

Bloodpack Needle Protector (BNP)  
Manufactured by ITL Corporation, PTY Ltd.  
BK980008

Medisystems Apheresis Needle with Guard  
Manufactured by Medisystems Corporation  
K932074

**Description of the device**

The AV Fistula Needle Protector (AVFNP) is a disposable, single-use, non-sterile needle protector, which is used as an aid in preventing accidental needle stick injuries upon completion of hemodialysis and apheresis procedures. The design of the AVFNP is compatible with currently marketed AV Fistula needle sets produced by most major manufacturers.

The hinged assembly allows the AVFNP to be included on AV Fistula needle sets at the time of manufacture or during a hemodialysis or apheresis procedure (i.e., before needle insertion or just prior to withdrawal). Once the AVFNP is clipped over the tubing, it can be engaged at any time by moving the AVFNP down the tubing to rest behind the butterfly wings of the AV Fistula needle. Prior to withdrawal of the needle, the AVFNP should be held securely between the index finger and thumb while the other hand pulls the tubing and needle assembly into the AVFNP. This position shields the point of the needle. A lock, an additional safety feature, can be activated once the needle has been shielded by pressing the top and bottom of the AVFNP together. This lock restricts further access to the needlepoint and contains any blood that may drop from the needle. An audible click can be heard when the lock is activated.

The AVFNP can be operated with either hand and leaves the other hand free to apply pressure to the puncture point and/or stabilize the AVFNP while withdrawing the needle. The AVFNP can be stabilized by holding, between the index finger and thumb, either the ribbed area on the front (e.g., when health care professional applies pressure to the puncture site during withdrawal of the needle) or the thumb rest on the back (e.g., when patient applies pressure to the puncture site during withdrawal of the needle).

**Intended Use**

The AV Fistula Needle Protector (AVFNP) is intended for use in the prevention of accidental needle stick injuries upon completion of hemodialysis and apheresis procedures.

**Comparison of device characteristics to predicate**

The table below provides a side-by-side comparison of the technological characteristics of the AVFNP and the following predicate devices: Bloodpack Needle Protector (BNP), BK980008, and Apheresis Needle with Needle Guard (ANNG), K932074.

<b>Technological Characteristics</b>			
<b>Characteristic</b>	<b>Predicate Devices: BNP and ANNG</b>	<b>Device: AVFNP</b>	<b>Comment:</b>
Intended Use	For use in preventing accidental needle stick injuries upon completion of hemodialysis and apheresis procedures. (ANNG)	For use in preventing accidental needle stick injuries upon completion of hemodialysis and apheresis procedures.	Same
Technological Features	The protector fits over the needle and tubing. The tubing is pulled with one hand until the assembly is locked into place. (BNP and ANNG)	The protector fits over the needle and tubing. The tubing is pulled with one hand until the assembly is locked into place.	Same
Specifications	Samples of various needle sizes, commonly used for the intended purpose of the device, were selected and tested to verify that the dimensions of the device allowed complete encapsulation of the needle and prevented finger access. It was determined that the specifications were adequate. (BNP and ANNG)	Samples of various needle sizes, commonly used for the intended purpose of the device, were selected and tested to verify that the dimensions of the device allowed complete encapsulation of the needle and prevented finger access. It was determined that the specifications were adequate.	Same
Materials	Polypropylene grades: GYM 28, GYM 45, and HD810P. (BNP)	Polypropylene grades: GYM 28, GYM 45, and HD810P.	Same
Sterilization	Not sterile. (BNP)	Not sterile.	Same

## **Conclusion**

The intended use, design, materials of fabrication, and performance are the same as the predicate devices, the Bloodpack Needle Protector (BNP), BK980008, and Apheresis Needle with Needle Guard, K932074. Therefore, the AVFNP is substantially equivalent to the Bloodpack Needle Protector (BK980008), the Apheresis Needle with Needle Guard (K932074), and devices marketed in interstate commerce prior to May 28, 1976.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 14 1999

ITL Corporation  
C/O Kenneth A. Palmer, Ph.D.  
Senior Technical Advisor  
Quintiles, Incorporated  
15825 Shady Grove Road, Suite 130  
Rockville, Maryland 20850-4008

Re: K991404  
Trade Name: Platypus AV Fistula Needle Protector (AVFNP)  
Regulatory Class: II  
Product Code: FMI  
Dated: April 22, 1999  
Received: April 22, 1999

Dear Dr. Palmer:

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.

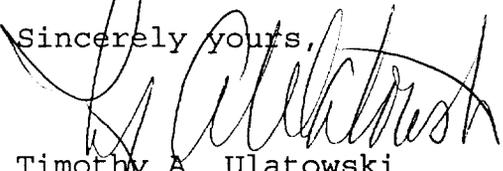
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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.

Page 2 - Dr. Palmer

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) Number**

None assigned as of this time

**Device Name**

AV Fistula Needle Protector (AVFNP)

**Indications for Use**

The AV Fistula Needle Protector (AVFNP) is intended for use in the prevention of accidental needle stick injuries upon completion of hemodialysis and apheresis procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

Over-the Counter Use

*Shari Newman for POC 7/14/99*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991404

- PRESCRIPTION  
USE