SEP 9 1999

K992091

10 510 (k) SUMMARY

This summary of Safety and Effectiveness is submitted in accordance with the requirements of 21 CFR 807.92

10.1 Establishment

Company	Bio-Plexus, Inc.
Address	129 Reservoir Road Vernon, CT 06066
Registration Number	1224632
Contact	Paul A. Tenthorey Regulatory Affairs Manager Phone 860 870 6112 Fax 860 870 6118

10.2 Device

Trade name	*PUNCTUR-GUARD* REVOLUTION™
Common Name	Blood Collection Needle Holder
Class	II
Performance Standard	Not listed in 21 CFR 860 - 897

10.3 Predicate Device

Trade Name	DROP-IT® Needle Holder
Company	Bio-Plexus, Inc.
510(k) Number	K963748
Marketing Approval	Received June 6, 1997

10.4 Description

The REVOLUTION Holder is designed to hold *PUNCTUR-GUARD*® Blood Collection Needles during blood drawing procedures, and to allow blunting of *PUNCTUR-GUARD*® needles prior to removal from the patient. Blunting reduces the probability of accidental needle sticks which are a major risk for infection with HIV or hepatitis. Blunting is performed by turning the dial at the holder's end.

The REVOLUTION Holder is non-sterile and can be used for up to 100 blood draws, including 20 cleanings. Contaminated needles can be released quickly in a one-handed operation by a manual push on the release button.

10.5 Intended Use

The REVOLUTION Holder is designed for use in blood drawing procedures. It is intended exclusively for use *PUNCTUR-GUARD®* Blood Collection Needles, and is compatible with standard blood collection tubes as well as pediatric inserts.

10.6 Performance Tests

Design and performance testing were executed in accordance with Design Control procedures (21 CFR 820.30; ISO 9001:1994). Tests were performed for holder integrity, needle insertion, holder/needle integrity, blunting and needle release. Tests included pass/fail evaluations and force and torque measurements. Complete functional testing in blood drawing procedures was performed by Bio-Plexus technical staff as well as by outside health care workers. Sample sizes reflected the significance of the particular functions, expressed in appropriate AQL levels. Potential failure modes and user errors were investigated and discussed in a risk analysis.

The test results demonstrated that the REVOLUTION Holder

- retains its integrity under forces that can be expected to occur in practical use,
- allows needle insertion by the health care worker in an acceptable torque range,
- allows blood draws in a reliable fashion,
- performs activation of the safety feature of *PUNCTUR-GUARD®* Blood Collection Needles in a consistent and fault-free manner,
- allows needle disposal by pushing a release button, and
- can be used for up to 100 uses, including 20 cleanings.

10.7 Conclusion; Substantial Equivalence

Safety, effectiveness and acceptability of the REVOLUTION holder were demonstrated by bench testing and simulated use testing.

Quantitative test values demonstrated the substantial equivalence of the REVOLUTION holder to the predicate device, the DROP-IT holder.

Paul A. Tenthorey

Paul A. Tenthorey, Ph.D.

Date: 6/18/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Paul A. Tenthorey, Ph.D.
Regulatory Affairs Manager
Bio-Plexus, Incorporated
129 Reservoir Road
Vernon, Connecticut 06066-5705

Re: K992091
Trade Name: Punctur-Guard Revolution™ Holder, Model 4750
Regulatory Class: II
Product Code: FMI
Dated: June 18, 1999
Received: June 21, 1999

Dear Dr. Tenthorey:

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.

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) 594-4690. 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

3.3 Indications for Use Statement

510(k) Number	K992091
Device Name	*PUNCTUR-GUARD* REVOLUTION™
Indications for Use	The REVOLUTION Holder is used in blood drawing procedures. It is used with *PUNCTUR-GUARD*® Blood Collection Needles only, and is compatible with standard blood sample tubes as well as pediatric inserts. The REVOLUTION Holder should be used by health care workers experienced in phlebotomy. At the end of a blood draw, the holder dial is rotated clockwise 90°. This rotation activates the safety mechanism of the *PUNCTUR-GUARD*® needle, which reduces the probability of an accidental needle stick. The needle can be eliminated quickly by a push on the release button. The holder is re-usable for up to 100 draws, including 20 cleanings.

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 Cucuzza
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992091