JUN - 6 1997

# 510(k) SUMMARY

K963748

Bio-Plexus Inc.
129 Resevoir Road
Vernon, CT 06066
CONTACT: Carl R. Sahi (President)

Date Submitted: 9/13/96 Revised: 11/27/96

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|---|---|
| *Proprietary Name:* | Bio-Plexus DROP-IT® Needle Holder |
| *Classification Name:* | Needle Holder |
| *Regulation #:* | 880.5570 |
| *Class:* | II |
| *Panel Code:* | 80 |
| *Product Code:* | FMI |
| *Reason for submission:* | New device |
| *Bio-Plexus Inc. Registration Number:* | 1224632 |

The Bio-Plexus DROP-IT® Needle Holder is a venipuncture needle holder comprised of an assembly of 5 plastic injection molded parts. The device rigidly holds a blood collection needle during the venipuncture procedure and also allows the needle to be released by use of a pushbutton rather than by unwinding. This device is for use with standard blood collection needles including Punctur-Guard® blood collection needles and winged sets. Standard blood collection needles include the Becton Dickinson Vacutainer® Needle, the Sherwood Monoject® Needle and the Terumo Venoject® Needle. The DROP-IT® Needle Holder performs the same functions as other legally marketed needle holders, for example, the Vacutainer® Brand Needle Holder #4893 and the Sage Products AutoDrop® Needle Holder #1510. The DROP-IT® Needle Holder is to be used by healthcare workers who are familiar with the art of phlebotomy in healthcare facilities or in the home healthcare setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 1997

Mr. Carl R. Sahi
President
Bio-Plexus, Incorported
P.O. Box 560
Vernon, Connecticut 06066

Re: K963748
Trade Name: Bio-Plexus Drop-it Needle Holder
Regulatory Class: II
Product Code: FMI
Dated: May 20, 1997
Received: May 23, 1997

Dear Mr. Sahi:

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) 594-4618. 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 at (301) 443-6597.

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 (if known): K963748

Device Name: BIO-PLEXUS DROP-IT® NEEDLE HOLDER

Indications For Use:

The Bio-Plexus DROP-IT® Needle Holder is a venipuncture needle holder which is recommended for use with standard blood collection needles including the PUNCTUR-GUARD® Blood Collection Needle as well as PUNCTUR-GUARD® Winged Sets for Blood Collection. It also mates with the Bio-Plexus Needle Disposal Container for easy needle disposal. This is a non-sterile reusable device recommended for a maximum of 100 uses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cucchi
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K963748

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

(Optional Format 1-2-96)