

2/9/99

K983411

Re: K983411, colorVees IV Sets

**510K Summary**

**Company Name:** VALNET Medical Corp.  
**Address:** Felicia Industrial Park (Playa)  
Street B Lot 16  
PO Box 859  
Santa Isabel, Puerto Rico  
00757-0859  
**Telephone:** (787) 845-2727  
**Contact Person:** Victor Ortíz, Vice-President and General Manager  
**Date:** 09/18/98

**Name of Device:** Intravascular Administration Set  
**Trade Name:** colorVees IV Set 20 drops/ml 105"  
colorVees IV Set 60 drops/ml 105"  
colorVees IV Set Vented 20 drops/ml 105"  
colorVees IV Set Vented 60 drops/ml 105"

**Usual Name:** Intravascular Administration Set  
**Classification:** FPA Class II Device

**For discussion only,  
Solo para discutirse**

**Predicate on legally marked device:**

BAXTER	2C5435s
McGaw	V1424
McGaw	V1515-15

**Description of the device:**

**Function:**

colorVees Intravascular Administration Set will be used to administer fluids from a container to a patient's vascular system through a needle or catheter. The

proposed device will enable the practitioner to identify and follow the colored multiple lines during the administration of intravenous solutions/medicaments.

**Basic Scientific Concept:**

This device is manufactured using different colored tubes. Its difference from predicated legally marked devices relies in this multiplicity of colored tubing. These colored tubes assist the practitioner to instantaneously identify and follow the delivery tubing when there is a need to run a plurality of intravascular administration sets to the same patient. The fundamental value added concept is to enlist color as an additional means of identification of tubing. This will greatly aid in preventing a practitioner from failing to make the proper identification of an IV tube from point of source (the IV solution itself) to point of delivery (venipuncture site on patient's body).

**Significant Physical and Performance Characteristics:**

There are no significant physical differences or performance characteristics from predicated devices. The only difference from predicated legally marked devices relies in its coloring. These colored tubes comply with biocompatibility requirements of FDA Blue Book Memorandum #G95-1 ISO 10993-1.

**Statement of how the technological characteristics compare to predicate or legally marked devices:**

The colorVees Intravascular Administration Set's technological characteristics are similar or compare to those of predicated devices. The only difference between the colorVees Intravascular Administration Sets and predicated legally marked devices relies in its coloring.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 9 1999

Mr. Victor Ortiz  
Vice-President and General Manager  
VALNET Medical Corporation  
Felicia Industrial Park (Playa)  
Street B Lot 16  
P.O. Box 859  
Santa Isabel, Puerto Rico 00757-0859

Re: K983411  
Trade Name: ColorVeas IV Sets  
Regulatory Class: II  
Product Code: FPA  
Dated: October 27, 1998  
Received: November 16, 1998

Dear Mr. Ortiz:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

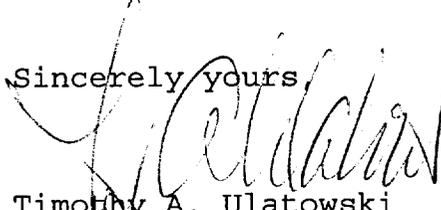
Page 2 - Mr. Ortiz

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) 594-4692. 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" (21CFR 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/dsma/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

K 983411

Re: K983411, colorVees IV Sets

Ver/3 - 4/24/96

Applicant: VALNET Medical Corp.

510 (k) Number (if known):

Device Name: colorVees Intravascular Administration Set

Indications for Use:

colorVees Intravascular Administration Set will be used to administer fluids from a container to a patient's vascular system through a needle or catheter. The proposed device will enable the practitioner to identify and follow the colored multiple lines during the administration of intravenous solutions/medicaments.

(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

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Patricia C. ...*

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

510(k) Number K 983411