510(k) Summary
(As required by 21 C.F.R. §807.92)

K030246

Submitted by:

Ileana Yanes
Victus, Inc.
4918 S.W. 74 Court
Miami, FL 33155
Tel: (305) 663 – 2129 ext. 102
Fax: (305) 663 – 1843

FEB 2 6 2003

Date of Summary: January 13, 2003

Device Name: Victus IV Administration Sets (Model Numbers 27071 and 27072)

Common Name: Intra Vascular Administration Set

Classification Name

Regulation Number	Classification Name
21 C.F.R §880.5440 ProCode 80 FPA	Intra Vascular Administration Set

Predicate Devices: BBraun/McGaw IV Administration Sets (Pre-Amendment, and as modified by K921860 and K93265), ICU Medical, Inc. standard or custom Clave® IV systems (K964435), and ICU Medical, Inc. Clave® Connector (K915571; K941190; and K970855).

Modifications: There are no modifications to the device design that affect safety and effectiveness of the Victus I.V. Administration Sets.

Device Description: The Victus I.V. Administration Sets are single use, sterile, non-pyrogenic devices used to administer I.V. fluids/medication to a patient's vascular system via gravity control.

Intended Use: The Victus I.V. Administration Sets provide a sterile fluid path for the intravenous administration of sterile intravenous fluid and/or intravenous medications from and I.V. container to a patient's vascular system via a catheter venous site. It is intennded for use on patients who require fluid/medication.

Technological characteristics: The Victus I.V. Administration Sets have the same technological characteristics as the legally marketed predicate BBraun McGaw and ICU Clave® IV Administrations Sets.

Testing: The Victus I.V. Administration Sets have undergone performance and safety testing to verify mechanical properties and biocompatibility using FDA recognised standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Ms. Ileana Yanes
Victus, Incorporated
4918 Southwest 74th Court
Miami, Florida 33155

Re: K030246
Trade/Device Name: Victus I.V. Administration
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 20, 2003
Received: January 24, 2003

Dear Ms. Yanes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K030246

510(k) Number
(if known)

Device Name Victus I.V. Administration Set

Indications for Use To administer IV fluids/medication to the patient's vascular system through a needle-free system that aids in the elimination of needle-stick injury.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K030246

Prescription Use ✓ OR Over-The-Counter Use_____