

NOV 24 1997

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SECTION 1.0 - 510(k) SUMMARY
CharterMed TPN/EVA Bag

August 13, 1997
Page 1 of 2

Applicant Name CharterMed Inc.
Address 1805 Swarthmore Avenue
Lakewood, NJ 08701
Contact Person K. Alice Preville, Director
Quality Assurance
Telephone (732) 901-9400, extension 17 (voice mail)
extension 23 (operator)
FAX (732) 901-9405

Device Nomenclature

- a. Trade Name CharterMed TPN-EVA Bags
- b. Common Name TPN bag
- c. Classification Name I.V. Container made of plastic used to hold a fluid mixture to be administered to a patient through an intravascular administration set (per 21 CFR 21 CFR 880.5025).

Predicate Device CharterMed Admixture Container for Total Parenteral Nutrition

Device Description empty TPN bags made from EVA (ethylene vinyl acetate) plastic film in sizes ranging from 100mL to 3000mL in capacity

Intended Use to allow the admixture and holding of total parenteral nutritional (TPN) solutions prior to and during intravascular administration to a patient.



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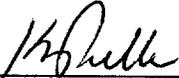
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Summary
of the
Technological Characteristics
as compared to the
Predicate Device

The proposed CharterMed device is an empty bag made from ethylene vinyl acetate (EVA) plastic film. The bag is intended for containment of total parenteral nutrition solutions and is substantially equivalent in design and intended use to comparable products currently in commercial distribution. Two (2) examples are provided below.

CharterMed currently manufactures and markets an empty TPN container made from TOTM plasticized poly vinyl chloride (PVC) under the tradename MIXME. FDA granted substantial equivalency to the MIXME product line in 1990 under 510(k) K902079.

Stedim Laboratories of Aubagne, France received notification of substantial equivalency for a comparable device made from ethylene vinyl acetate (EVA) plastic film under 510(k) K911567. The device is referred to as the "Stedim TPN Bag - Dual E.V.A. empty container for parenteral admixtures designed for use with automated compounding devices".



K. Alice Preville, Director
Quality Assurance

10/21/97
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. K. Alice Preville
Director, Quality Assurance
Chartermed, Incorporated
1805 Swarthmore Avenue
Lakewood, New Jersey 08701

NOV 24 1997

Re: K973103
Trade Name: Chartermed TPN-EVA Bags
Regulatory Class: II
Product Code: KPE
Dated: September 25, 1997
Received: September 26, 1997

Dear Ms. Preville:

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.

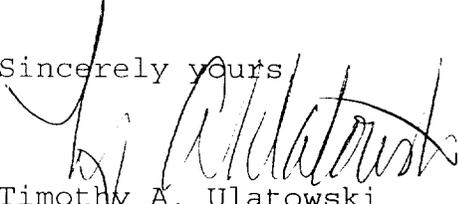
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

K973103

510(k) Number (if known): __ K973103 __

Device Name: CharterMed TPN-EVA Bags

Indications for Use:

Empty bags made from ethyl vinyl acetate (EVA) film intended to contain total parenteral nutrition (TPN) solutions and compatible medications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Optional Format 1-2-96)