EMMEBI
MEDICAL TECHNOLOGICAL APPLICATIONS

FEB - 4 2005

PREMARKET NOTIFICATION
510(K) SUMMARY

K043446
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SUMMARY OF SAFETY AND EFFICACY

A. The submitter's name, address, telephone number, contact person and date of preparation.

Submitter's Name:	Emmebi, srl
Submitter's Address:	Via Albettoniera, 50/E
	35030 Bastia Di Rovolon
Submitter's Phone Number	(614) 501-9340 (800) 338-0855
Contact Person:	Marjorie Bush
Contact Person's Phone Number:	(616) 957-1677
Date of Preparation:	11/01/04

B. The name of the device including trade or proprietary name if applicable, the common or usual name and the classification name.

Name:	Central Venous Catheter with Lestep® Introducer
Brand:	EmmeBi Central Venous Catheter with Lestep® Introducer
1. Common Name:	Emmebi Central Venous Catheter
Classification Name:	Intravascular Catheter
2. Common Name:	Guidewire
Classification Name:	Catheter guidewire
3. Common Name:	Lestep® Introducer
Classification Name:	Intrroducer, Catheter

C. An identification of the predicate or legally marketed device(s) to which substantial equivalence is claimed:

Predicate Device: Arrow International	Arrowg+ard Blue Plus Multi-Lumen Central Venous Catheter
Predicate Device: Cook Critical Care	Triple Lumen Central Venous Catheter
Predicate Device: Medcomp	Quad Lumen Central Venous Catheter
Predicate Guidewire: Lake Region Mfg., Inc.	K963320
Predicate Introducer Raulerson Syringe	K971281 – One Step Guidewire Insertion Bulb Needle
Predicate Introducer Micro Stick	Unknown

D. A description of the device that is the subject of the Premarket Notification submission:

The Emmebi Central Venous Catheter Kit is comprised of three main components; 1. Syringe/inserter 2. guidewire (J-Wire) and 3. central venous catheter. The catheter kit is intended for short term use as an aid to access the central venous system.

The Syringe/inserter simplifies the technique used by physicians to perform catheterization.

The guidewire (J-Wire) is designed to fit inside a percutaneous catheter for the purpose of directing the catheter being introduced.

The catheters are available in 14→ 22 gauge sizes with 4, 5, 6 and 7 Fr. diameter sizes in either a single, double or triple lumen. Circular lumen passages have soft flexible tapered tips. Lumens are connected to extensions containing hubs and catheter fixing wings. The lumens are printed with depth markings. Catheter markings are radiopaque.

E. Statement of intended use of the device:
The EmmeBi Central Venous Catheter with Lestep® Introducer is intended for short term use as an aid for the catheterization of the superior vena cava for the purpose of performing parenteral infusional or nutritional therapy and to withdraw blood samples where the peripheral venous system is not practicable.

F. Statement of how the technological characteristics compare to those of the predicate or legally marketed device identified in 510K submission:

The technological characteristics of Emmebi' s Central Venous Catheter Kit with Lestep® Introducer are substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, materials, performance, manufacturing process and sterilization method.

G. Performance data for the Emmebi Central Venous Catheter Kit with Lestep® Introducer including tensile strength, bond strength test, bend test, air and liquid leakage, performance demonstrate that this device is substantially equivalent to legally marketed devices intended for central venous catheterization.

David L. Yoder
Statutory Agent/EmmeBi, srl

1/18/05
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2005

Emmebi SRL
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K043446
Trade/Device Name: Emmebi Central Venous Catheter Kit with Lestep® Introducer
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 18, 2005
Received: January 21, 2005

Dear Mr. Devine:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(K) Number: K043446

Device Name: Emmebi Central Venous Catheter Kit with Lestep® Introducer

Indications for Use:

The EmmeBi Lepstep Central Venous Catheter Kit is intended for short term use as an aid for catheterization of the superior vena cava for the purpose of performing parenteral infusional or nutritional therapy and to withdraw blood samples where the peripheral venous system is not practicable.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a Physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ___√___ Over-the-Counter Use: _____

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

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