JAN 0 7 2003

Attachment #6

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K021130

1. Submitter's Identification:

Special Medical Co. Ltd.
No. 3 Industrial Building, National
Hi-Tech Development Zone
GangKou Road
Guangdong 528041, China

Contact: Dr. Yung-jin Lee

Date Summary Prepared:

April 5, 2002

2. Name of the Device:

SPECATH® Central Venous Catheter Kits

3. Predicate Device Information:

1. K#963257, Peripherally Inserted Medline Catheter, Arrow International, Inc.
2. K#900263 Anti-Microbial Multi-Lumen Central Venous Catheter, Arrow International, Inc.
3. K#971085, Soft Tip Multi-Lumen Central Venous Catheter, B. Braun Medical, Inc.

4. Device Description:

SPECATH® catheters are polyurethane, radiopaque single or multiple (up to 4) lumen catheters. The size of catheters are from 4 French through 12 French and lengths 10 cm through 30 cm. Each lumen extends from the vicinity of the distal tip to the main (bifurcation or junction) hub, where it branches into dedicated extension lines. The extension line hubs are labeled to provide positive identification of the lumen size and location. The catheter body has depth markings, measured in cm from the catheter tips. The extension line marked "distal" is used for device placement using a guide wire and then to infuse fluids.

The distal tip is soft to minimize patient trauma during insertion. The device is radiopaque to allow verification of location in the patient.

Central venous catheters are inserted into a large vein and threaded into the central venous system. To reduce the chance of complications, the central venous catheter tip should be placed in the superior vena cava above its junction with the right atrium with the distal catheter parallel to the vessel wall. For reference, the distal tip should be positioned at a level above either the azygos vein or the carina of the trachea whichever is better visualized.

The accessories described below will be included in the SPECATH® Central Venous Catheter Kits.

a. Guidewires: The guidewire is used for guiding the catheter through the venous system to the desired catheter placement location. According to the different sizes of the catheters, varying size guidewire will be included in the kit: Diameters are 0.018", 0.021", 0.035"; Lengths are 450mm (45cm), 500 mm (50cm), 700mm (70cm), 1500mm (150 cm).

b. Vessel Dialators: Dialators are used to enlarge the introducer path of the catheter. According to the size of the catheter, there will be a corresponding dialator with different size and effective lengths.

c. Introducer: The introducer is used for entrance and tunneling into the skin and vascular system for the purpose of catheter placement. According to the size of the catheter, the following introducers will be included: 18 Ga, 70 mm; 19 Ga, 45 mm; 20 Ga, 45 mm.

d. Syringe: A 5 ml. Syringe manufactured by Becton Dickinson and used to infuse fluids into the catheter will be included in the kit.

e. Injection Caps: The injection cap is connected to the female luer hubs of the extension tubes.

5. Intended Use:

SPECATH® Central Venous Catheters are intended for the purpose of providing short term access (less than 30 days) to the vascular system for the infusion of fluids, monitoring of pressures, and/or sampling of blood.

6. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing to Support Substantial Equivalence included:

- **Surface**
- **Size**
- **Distance Markings**
- **Lumen Markings**
- **Primary Volume Test**
- **Break Force**
- **Flow Rate**
- **Burst Pressure Test**
- **Leakage**
- **Tensile Strength Test**
- **Radio-detectability**
- **Hub Liquid Leakage**
- **Hub Air Leakage**
- **Hub Separation Force**
- **Hub Stress Cracking**
- **Label Information**

7. **Discussion of Clinical Tests Performed:**

Not applicable as there are no new indications for use which must be supported by clinical data.

8. **Conclusions:**

The subject device, SPECATH® Central Venous Catheter Kits, has the same intended use and characteristics as a combination of the predicate devices. Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrates that there are no difference in their technological characteristics, thereby not raising any new question of safety and effectiveness. Thus, the SPECATH® Central Venous Catheter Kits are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

Special Medical Company Limited
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K021130
Trade/Device Name: SPECATH® Central Venous Catheter Kits
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 22, 2002
Received: November 26, 2002

Dear Ms. Falk:

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. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021130

Device Name SPECATH® Central Venous Catheter Kits

Indications For Use:

SPECATH® Central Venous Catheters are intended for the purpose of providing short term access (less than 30 days) to the vascular system for the infusion of fluids, monitoring of pressures, and/or sampling of blood.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Y
(Per 21 CFR 801.109) **OR** **Over-The-Counter Use** ____
(Optional Format 1-2-96)

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

510(k) Number K021130