

K070451  
1.F3

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: \_\_\_\_\_

JUL 31 2007

### 1. Applicant Device Information

**Trade/Proprietary Name:** Able Central Venous Catheter

**Models:**

14 G, 16 G, 18 G, and 20 G in single-lumen catheters;

4 F, 5 F, 7 F and 8 F in double-lumen catheter;

5.5 F and 7 F in triple-lumen catheter;

**Common Name:** Central Venous Catheter

**Classification Name:** Catheter, Intravascular, Therapeutic, Short-term less than 30 days

**Device Class:** II

**Product Code:** FOZ

**Regulation Number:** 880.5200

**Intended Use:**

The Central Venous Catheters are intended for vascular access infusion and withdrawal of blood, blood products, and fluids, central venous blood pressure monitoring (CVP), plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drug infusion.

### 2. Submitter Information

**Establishment Registration Name:**

Foshan Nanhai Bai He Medical Technology Co., Ltd.

No. 14 Haier Road, Guicheng, Nanhai District,

Foshan City, Guangdong Province

China

**Phone:** +86-757-86280075

**Fax:** +86-757-86397179

**Contact Person of the Submission:**

Ms. Diana. Hong

Shanghai Mid-link Consulting Co., Ltd.

1404, No 34, Lane 255 Wanping Road (S),

Shanghai 200032

China

**Phone:** +86-21-64264467 x 152

**Fax:** +86-21-64264468 x 809

**Email:** Diana.hong@mid-link.net

### 3. Predicate Device

**a) Predicate device for single-lumen and double-lumen**

SPECATHB Central Venous Catheter Kits (K021130)

**Manufactured by:**

Special Medical Co. Ltd

No. 3 Industrial Building, National

Hi-Tech Development Zone

GangKou Road

Guangdong 528041,

China

**b) Predicate device for triple-lumen**

Sunder Central Venous Catheter Kit (K024007)

**Manufactured by:**

Sunder Biomedical Tech. Co., Ltd

1 OF- 1, 1-67, Wu-Chuan Rd.,

Taichuns. Taiwan 403

China

### 4. Device Description

Able® Central Venous Catheter is a polyurethane central venous catheter which is intended to insert into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously.

All the variants of applicant devices: single-lumen, double-lumen, and triple-lumen. There are outer diameter dimensions of 14 G, 16 G, 18 G, and 20 G in single-lumen catheters, 4 F, 5 F, 7 F and 8 F in double-lumen catheter, and 5.5 F and 7 F in triple-lumen catheter.

The applicant device mainly consists of 5 parts: distal end, catheter body of effective length, catheter junction, extension cannula, and catheter hub. Distal end is soft and flexible, which is intended to be located within the patient's vena cava. Catheter body of effective length is tubular and with no-communication single or multiple lumens. Catheter junction attaches catheter body of effective length and extension cannula. At the end of the extension cannula, there is female catheter hub for the connection.

16070451  
3.73

## 5. Test Data

The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the component material in the finished product was provided.

The applicant devices conform to ISO 10555-1 and ISO 10555-3.

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, Radiodetectability, Hub Liquid Leakage, Hub Air Leakage, Hub Separation Force, Hub Stress Cracking, Label Information

## 6. Substantially Equivalence

### Comparison Analysis:

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety.

### Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 31 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Foshan Nanhai Bai He Medical Technology Company, Limited  
C/O Ms. Diana Hong  
Shanghai Mid-Link Business Consulting Company, Limited  
Suite 8D, No.19 Lane 999,  
Zhong Shan Nan Er Road  
Shanghai, China 528200

Re: K070451

Trade/Device Name: Able Central Venous Catheter

Regulation Number: 880.5200

Regulation Name: Intravascular Catheter

Regulatory Class: II

Product Code: FOZ

Dated: June 21, 2007

Received: July 19, 2007

Dear Ms Hong:

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.

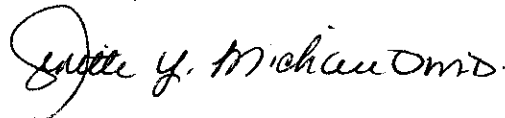
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

A handwritten signature in black ink, appearing to read "Jui-Lin Chiu", written in a cursive style.

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

K070451

1-P1

## Indications for Use

510(k) Number: \_\_\_\_\_

Device Name: Able Central Venous Catheter

### Indications for Use:

The Central Venous Catheters including:

14 G, 16 G, 18 G, and 20 G in single-lumen catheters;

4 F, 5 F, 7 F and 8 F in double-lumen catheter;

5.5 F and 7 F in triple-lumen catheter;

are intended for vascular access infusion and withdrawal of blood, blood products, and fluids, plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drug infusion.

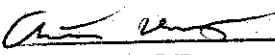
Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K070451