SEP 22 1998

DUAL PURPOSE CLOSED CATHETER
510(k) Premarket Notification
Spirit Medical Systems, Inc.

510(k) SUMMARY K982945

Date Summary was Prepared August 14, 1998

Peter M. Fitzgerald
Printed name of person required to submit 510(k)

Peter M. Fitzgerald
Signature of person required to submit 510(k)

PRESIDENT
Title of person submitting 510(k)

Submitter:

SPIRIT MEDICAL SYSTEMS, INC.
16267 Whitestone Dr.
Parker, CO. 80134
(303) 840-1299

Establishment Registration Number:

Spirit Medical Systems, Inc. is not currently registered with the FDA. Spirit Medical Systems, Inc. will submit form FDA-2891A (Initial Registration of Device Establishment), to the Food and Drug Administration prior to establishing a manufacturing facility.

Proprietary Name:	DUAL PURPOSE CLOSED CATHETER
Common/Usual Name:	Dual purpose oxygen/suction catheter
Classification Name:	Tracheobronchial Suction Catheter
Classification:	Dual purpose oxygen/suction catheter systems such as DUAL PURPOSE CLOSED CATHETER falls under the classification of 21 CFR 868.6810 "Tracheobronchial suction catheter" regulatory Class I.
Predicate device:	The predicate device is Jinotti™ Closed Suction/Oxygen Catheter, (510(k) #K833375) manufactured and distributed by MedCare Medical Group, Inc.

510(k) Summary - continued

Description of 510(k) submission device:

Product Description:
The Spirit Medical Systems, Inc. DUAL PURPOSE CLOSED CATHETER is a disposable sterile dual purpose catheter designed to provide both the functions of suctioning and supplying oxygen into the patient's trachea through an endotracheal tube. The first function provides maximum suction efficiency into the airway without compromising sterility and patient safety. The second function provides additional gas flow into the airway for the purpose of improving alveolar ventilation prior to and immediately following suctioning.

Intended use:
The Spirit Medical Systems, Inc. DUAL PURPOSE CLOSED CATHETER is a disposable sterile dual purpose catheter designed to provide both the functions of suctioning and supplying oxygen into the patient's trachea through an endotracheal tube. The first function provides maximum suction efficiency into the airway without compromising sterility and patient safety. The second function provides additional gas flow into the airway for the purpose of improving alveolar ventilation prior to and immediately following suctioning.

Comparison to Predicate Device:
The Spirit Medical Systems, Inc. DUAL PURPOSE CLOSED CATHETER and the above named substantially equivalent device have the same intended use in that they are a disposable sterile dual purpose closed oxygen/suction catheters designed to provide both the functions of suctioning and supplying oxygen into the patient's trachea through an endotracheal tube. Both the DUAL PURPOSE CLOSED CATHETER and the Jontti™ Closed Suction/Oxygen catheter provide maximum suction efficiency into the airway without compromising patient safety as well as additional gas flow into the airway for the purpose of improving alveolar ventilation, prior to and immediately following suctioning,

Summary of Performance Testing:
Based on the results of performance testing conducted at HAUSER Laboratories the Spirit Medical Systems, Inc. DUAL PURPOSE CLOSED CATHETER is substantially equivalent to the Jinotti™ Closed Suction/Oxygen Catheter Systems manufactured and distributed by MedCare Medical Group, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Mr. Jeffrey T. Sawyer
Spirit Medical Systems, Inc.
16267 Whitestone Drive
Parker, CO 80134

Re: K982945
Dual Purpose Closed Catheter
Regulatory Class: I (one)
Product Code: BSY
Dated: August 17, 1998
Received: August 21, 1998

Dear Mr. Sawyer:

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 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). 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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K982945

DEVICE NAME :

INDICATIONS FOR USE:

The Spirit Medical Systems, Inc. DUAL PURPOSE CLOSED CATHETER is a disposable sterile dual purpose catheter designed to provide both the functions of suctioning and supplying oxygen into the patient's trachea through an endotracheal tube. The first function provides maximum suction efficiency into the airway without compromising sterility and patient safety. The second function provides additional gas flow into the airway for the purpose of improving alveolar ventilation prior to and immediately following suctioning.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K982945