MAY 21 2001

510(k) SUMMARY K003187 WMB

510(k) NUMBER: PENDING

SUBMITTED BY: AutoCath Vascular Access, Inc.

CONTACT PERSON:

Tom Gardner
Auto/Cath Vascular Access, Inc.
21092 Bake Parkway, Suite 110
Lake Forest, CA 92630
Phone: (949) 206-9911
Fax: (949) 206-9915

DATE OF PREPARATION: October 5, 2000

NAME OF DEVICE: I.V. Catheter Introducer

CLASSIFICATION NAME: Catheter, Intravascular, Therapeutic, Short-term (< 30 days). (21 CFR 880.5200)

TRADE NAME: VacuCath™ I.V. Catheter Introducer

PREDICATE DEVICES:

1. Quik-Cath® (510k # unknown), Baxter Healthcare Corporation, Deerfield, Illinois.
2. AngioCath® (510k # unknown), Deseret Medical, Inc., Becton Dickinson and Company, Sandy, Utah.
3. Insyte™ (K921845, K952861 or K984059), Becton Dickinson, Sandy, Utah.
4. Protectiv® IV Safety System (K962226) Johnson & Johnson Medical, Arlington, Texas.
5. SafeCath™ (K880260), Phase Medical Systems, Santa Ana, California.

INDICATION FOR USE:

The AutoCath I.V. Catheter Introducer is indicated for use in the placement of I.V. Catheters to provide access to veins or arteries for the delivery of medications and fluids, to sample blood or to monitor blood pressure.

SUMMARY STATEMENT:

The VacuCath I.V. Catheter Introducer is indicated for use in the placement of I.V. catheters to provide access to blood vessels for the delivery of medications and fluids, to sample blood or to monitor blood pressure. The VacuCath I.V. Catheter Introducer is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed. The VacuCath is a sterile, peripheral intravenous (IV) catheter introducer designed to facilitate the placement of an I.V. catheter. The device is similar in size, weight and appearance to other

currently available IV catheter introducers. The system has integrated features to enhance normal catheter placement and protection from accidental needlesticks. The VacuCath is designed for use with either hand using a one-handed technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Ms. Anil Bhalani
Regulatory Affairs Consultant
Auto/Cath Vascular Access, Incorporated
21092 Bake Parkway
Lake Forest, California 92630

Re: K003187
Trade/Device Name: VacuCath I.V. Catheter Introducter
Regulation Number: 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: February 27, 2001
Received: March 1, 2001

Dear Mr. Bhalani:

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) 594-4692. 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 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,

Susan Runner

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

Enclosure

INDICATIONS FOR USE

AutoCath Vascular Access is providing this separate cover page for the VacuCath I.V. Catheter Introducer "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K003187

Device Name: VacuCath I.V. Catheter Introducer

Indications for Use: The AutoCath I.V. Catheter Introducer is indicated for use in the placement of an I.V. Catheter to provide access to blood vessels for the delivery of medications and fluids, to sample blood or to monitor blood pressure.

Signature: _____ Title: *President and CEO* Date: *10-5-00*

(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)

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

510(k) Number K003187