K981547

JUN 18 1998

June 11, 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act and CFR 807.92.

Trade Name: NFC Needlefree Y-Site
Common Name: Y-Injection Site
Classification Name: Intravascular Administration Set (accessory)

The Filtertek NFC Needlefree Y-Site is intended for single patient use and intended for placement between the male Luer connection of a primary solution source and the patient's vascular access device. In this position, the y-site body provides unobstructed flow between the fluid source and the patient. The needlefree side port of the y-site can be swabbed and then accessed multiple times. The closure system has been tested and has been found to maintain line patency throughout the labeled duration of use.

The Filtertek NFC Needlefree Y-Site is a sterile, non-pyrogenic component packaged in a Tyvek/polyethylene form, fill, and seal package. The materials used to manufacture the Filtertek NFC Needlefree Y-Site have been tested per tripartite guidelines and are safe for their intended use. The indicated use of the NFC Needlefree Y-Site is the same or the equivalent of the predicate device named in this submission. The named predicate device in this submission is the Douglas Medical products Maxcess™ Needlefree Y-Site currently marketed by Douglas Medical Products under 510(k) #K970800. The Filtertek NFC Needlefree Y-Site is sterilized per AAMI guidelines to a 10^{-6} sterility assurance level. Each production lot is LAL tested per USP guidelines.

Based on the fact that the Filtertek NFC Needlefree Y-Site utilizes similar and equivalent designs and materials as currently legally marketed products, it is safe and effective when used as intended.

Sincerely,

Larry Larkin
Regulatory Affairs Administrator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1998

Mr. Larry Larkin
Regulatory Affairs Administrator
Filtertek, Incorporated
11411 Price Road
P.O. Box 310
Hebron, Illinois 60034

Re: K981547
Trade Name: NFC Needlefree Y-Site, Model 69970
Regulatory Class: II
Product Code: FPA
Dated: April 17, 1998
Received: April 30, 1998

Dear Mr. Larkin:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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/dsmamain.html".

Sincerely yours,

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

Enclosure

K981547

510(K) Number (if known): To be assigned

Device Name: NFC Needlefree Y-Site

Indications For Use:

The NFC Y-Site is for single patient use and intended for placement between the male Luer connection of a primary solution source and the patient's vascular access device. In this position, the y-site body provides unobstructed flow between the fluid source and the patient. The Needlefree side port of the y-site is swabbable and can be accessed multiple times using a male Luer for the purpose of administering general IV solutions or blood.

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

Concurrence of CDRH, Office of Device evaluation (ODE)

(Division Sign-Off) B. Burke
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981547

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)