

K981548

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 Connector

Common Name: Needleless injection port or needlefree injection site

Classification Name: Intravascular Administration Set

The Filtertek NFC Needlefree Connector is intended to be used as a needleless injection port that can be attached to a luer lock connector. It is intended for single patient use and can be swabbed and then accessed multiple times. The closure has been tested and has been found to maintain line patency throughout the labeled duration of use.

The Filtertek NFC Needlefree Connector is a one-piece design. luer interfacing injection port. It is sterile, nonpyrogenic and packaged in a Tyvek/polyethylene form, fill, and seal package. The materials used to manufacture the Filtertek NFC Needlefree Connector have been tested per tripartite guidelines and are safe for their intended use. The indicated use of the NFC Needlefree Connector is the same or the equivalent of the predicate device named in this submission. The named predicate devices in this submission are Douglas Medical products MaxcessTM Connector currently marketed by Douglas Medical Products under 510(k) #K960661, and the ClaveTM Connector currently marketed by ICU Medical, Inc under 510(k) #K915571. The Filtertek NFC Needlefree Connector 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 Connector utilizes similar and equivalent designs and materials as currently legally marketed products, it is safe and effective when used as intended.

By:



Larry Larkin
Regulatory Affairs Administrator



JUN 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981548
Trade Name: NFC Needlefree Connector Model 69960
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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

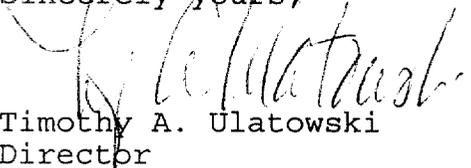
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

