

MAY 14 1999

ACT Medical FlexNeedle® Plus  
510(k) April 29, 1999

K990693

### 13. 510(K) SUMMARY

- (1) ACT Medical  
150 California Street  
Newton, MA 02458

Contact Person: Wendy Shotts  
Date Summary Prepared: February 26, 1999

- (2) Trade or Proprietary Name: FlexNeedle® Plus  
Common Name: Intravascular Administration Set  
Classified Name: Intravascular Administration Set
- (3) Predicates: Luther L-Cath (K# unknown)  
Bard Access Systems Winged Infusion Set (K# unknown)
- (4) Description of Device: The FlexNeedle Plus is comprised of a flexible catheter, a body with elastomeric septum and side port; sidearm tubing with a luer infusion fitting, cap and pinch clamp; and an insertion stylet with a safety housing for capturing the sharp upon removal.
- (5) Intended Use: The FlexNeedle Plus is intended for use in the short term or intermittent transcutaneous cannulation of implanted venous access ports and is designed with the purpose of reducing accidental needlesticks.
- (6) The FlexNeedle Plus has the same technological characteristics as the predicate devices in that it is a hollow tube with a luer fitting intended to remain in a subcutaneous access port in order to provide access to the bloodstream.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 14 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Wendy V. Shotts  
Quality Engineer  
Act Medical, Incorporated  
150 California Street  
Newton, Massachusetts 02458

Re: K990693  
Trade Name: FlexNeedle® Plus  
Regulatory Class: II  
Product Code: FPA  
Dated: March 2, 1999  
Received: March 3, 1999

Dear Ms. Shotts:

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.

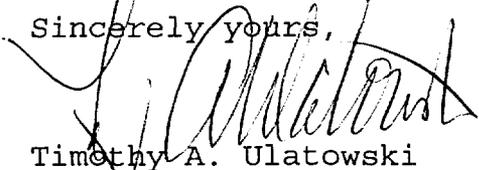
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

K990693

**Center for Devices and Radiological Health**

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

Device Name: Flex Needle ® Plus

Indications for Use:

The Flex Needle ® Plus is intended for use in the short term or intermittent transcutaneous cannulation of implanted venous access ports and is designed with the purpose of reducing accidental needlesticks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Alexis Raveneau for PXC 5/14/99*

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

510(k) Number K990693

PRESCRIPTION  
DEVICE (TV)

(Optional Format 3-10-98)

(Posted July 1, 1998)

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