



916-342-4133  
FAX: 916-343-4541

MAR 19 1998

K963794

01 September 1996

### 510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Needle, aspiration and injection, disposable, or biopsy instrument, gastroenterology-urology.

Common/usual name: Aspiration needle, puncture needle, probe needle, irrigation needle, injection needle, etc.

Proprietary name: PunctureNeedle

B. Substantial equivalence: Terumo (K760775), Wilson-Cook (K851953, K851957), Daum (K961185), and others.

C. Device description: The PunctureNeedle is a standard needle to puncture precise anatomical locations and inject or aspirate various fluids or contents.

D. Intended use: The PunctureNeedle is intended for use in puncturing precise anatomical locations (including but not limited to cysts, lesions, fluid spaces, etc.) and aspirating or injecting various fluids or contents. The

device may be utilized under MRI guidance.

- E. Technological characteristics: The PunctureNeedle is similar to predicate devices in its design, function, and intended use.

The proposed device is different than many needles in that the PunctureNeedle device has components manufactured of titanium alloy, which yields less artifact than stainless steel when utilized under magnetic resonance conditions.

Submitted,  
FERGUSON MEDICAL  
Establishment Registration Number 2937794

A handwritten signature in cursive script that reads "Frank Ferguson". The signature is written in dark ink and includes a long horizontal flourish extending to the right.

Frank Ferguson  
Official Correspondent



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 19 1998

Mr. Frank Ferguson  
Ferguson Medical  
3407 Bay Avenue  
Chico, California 95973

Re: K963794  
Trade Name: PunctureNeedle  
Regulatory Class: II  
Product Code: KNW  
Dated: December 27, 1997  
Received: January 5, 1998

Dear Mr. Ferguson:

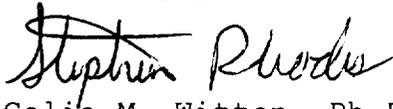
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 current Good Manufacturing Practice requirement, 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) 594-4595. 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,

*for* 

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (If known): K963794

Device Name: PunctureNeedle

Indications For Use:

The PunctureNeedle device is intended for use in puncturing precise anatomical locations (including but not limited to cysts, lesions, fluid spaces, etc.) and aspirating or injecting various fluids or contents. The device may be utilized under MRI guidance.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Stephen Rhodes*

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K963794

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_