DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Ms. Debora D. Hinman
Senior Director, Regulatory Affairs
PercuSurge Incorporated
777 N. Pastoria Avenue
Sunnyvale, CA 94086

Re: K972777 NSE Appeal
Trade Name: PercuSurge Temporary Occlusion Balloon (TOB) System
Regulatory Class: II
Product Code: MJN
Dated: May 20, 1998
Received: May 21, 1998
Amended: May 28, June 29, and August 5, 1998

Dear Ms. Hinman:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Indications and Warnings section of the device's labeling:

1. INDICATIONS AND INTENDED USE:

The PercuSurge Temporary Occlusion Balloon (TOB) System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids with or without vessel occlusion.

The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature (see WARNINGS).

2. In bold and first to appear in the WARNINGS section,

WARNINGS:

The safety and effectiveness of the PercuSurge Temporary Occlusion Balloon (TOB) System, used as an adjunct in interventional procedures, have NOT been established. Complications from the use of the device in this manner could lead to death, permanent impairment, and/or the need for emergency surgical intervention.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k)

premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972777

Device Name: PercuSurge Temporary Occlusion Balloon (TOB) System

FDA's Statement of the Indications For Use for device:

The PercuSurge Temporary Occlusion Balloon (TOB) System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids with or without vessel occlusion.

The safety and effectiveness of this device have not been established in the coronary, cerebral, or carotid vasculature (see WARNINGS).

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)