EXHIBIT G:

510(k) SUMMARY – (21 CFR § 807.92(c))

Submitter's Name and Contact Information
Windy Hill Technology, Inc. ("WHT")
1010 Hamilton Court
Menlo Park, California 94025
Telephone: 650.566.2330
Facsimile: 650.566.2345

Contact Person
Angela B. Soito, Regulatory and Quality Affairs Manager

Summary Preparation Date
October 30, 1998

Device Names

Trade Name:	Windy Hill Technology Fuji Catheter
Common Name:	Breast Duct Catheter
Classification Name:	Manual Surgical Instrument (21CFR § 878.4800)

Substantially Equivalent Devices
Substantial Equivalence was claimed to the Manan™ Galactography Kit, the Manan™ Chiba Needle and the Manan™ Acura Breast Localization Needle.

Device Description
The Windy Hill Technology Fuji Catheter is a dual lumen device with a flexible shaft. The hub located at the proximal end of the Fuji Catheter has two branches which each correspond with a single port. The entry port is used for saline or contrast infusion and is marked with an arrow pointing in the distal direction of the catheter. The corresponding entry lumen is located at the distal end of the catheter, adjacent to the 1 cm marker. The exit port is used for fluid collection and for guidewire introduction and is marked with an arrow pointing in the proximal direction of the catheter. The corresponding exit lumen is located at the distal tip of the catheter. The device is provided sterile and is intended for single use only.

Intended Use
The Windy Hill Technology Fuji Catheter is designed to perform contrast enhanced radiography of breast milk ducts. It may also be used for the collection of cells and/or fluid for cytological evaluation.

Technological Characteristics
The Windy Hill Technology Device is substantially equivalent to the Manan™ Galactography Kit, the Manan™ Chiba Needle and the Manan™ Acura Breast Localization Needle. The main difference between the subject and predicate devices is that the WHT device contains two device lumens which combines the functions of the predicate devices to allow for fluid infusion and fluid collection.

Data Supporting Substantial Equivalence
WHT conducted laboratory, preclinical and clinical testing to demonstrate the safe and effective use of the WHT Device. Laboratory testing was conducted to evaluate specific device performance parameters and, in some cases, to compare these results with those obtained with a predicate device. Performance was also evaluated in preclinical testing using a human cadaver model. Clinical testing was conducted to evaluate human use of the device in pre-mastectomized or lumpectomized breasts. This testing supported that use of the Windy Hill Technology Fuji Catheter is both safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 1999

Ms. Angela B. Soito
Regulatory and Quality Affairs Manager
Windy Hill Technology, Inc.
1010 Hamilton Court
Menlo Court, California 94025

Re: K983867
Trade Name: Windy Hill Technology Fuji Catheter
Regulatory Class: II
Product Code: KNW
Dated: April 27, 1999
Received: April 29, 1999

Dear Ms. Soito:

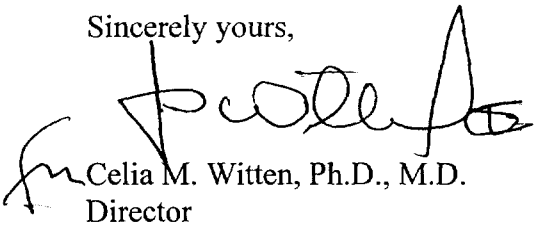
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

EXHIBIT H:

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983867

Device Name: Windy Hill Technology Fuji Catheter

Indications for Use:

The Fuji Catheter is designed to perform contrast enhanced radiography of breast milk ducts. It may also be used for the collection of cells and/or fluid for cytological analysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983867