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,
Director, Regulatory and Quality Affairs

Summary Preparation Date
September 30, 1999

Device Names

Trade Name:	Windy Hill Technology DucPrep™ Breast Aspirator
Common Name:	Breast Aspirator
Classification Name:	Gastroenterology-Urology Biopsy Instrument (21CFR § 876.1075)

Substantially Equivalent Devices
Substantial Equivalence was claimed to the Diagnostic, Inc. Breast Aspirator, the WHT Fuji Catheter and nonpowered breast milk pumps.

Device Description
The Windy Hill Technology DucPrep breast aspirator device is similar to nonpowered breast pumps used to express milk in lactating women. The device is comprised of a rigid polycarbonate cup which is connected to a small piece of polymer tubing. A flexible, silicone insert is placed inside of the rigid polycarbonate cup prior to device placement around the breast nipple. The tubing is attached to a standard syringe which is used to pull a gentle vacuum to express breast ductal fluid. The device is packaged in a Tyvek® pouch.

Intended Use
The DucPrep device is used to elicit fluid from multiple ductal orifices for subsequent cytological evaluation or to identify ductal orifices for subsequent cannulation with the WHT Fuji Catheter.

Technological Characteristics
The DucPrep device is substantially equivalent to the Diagnostic, Inc. Breast Aspirator, the WHT Fuji Catheter and nonpowered breast milk pumps. The subject device differs from the WHT Fuji Catheter in that the latter device is a catheter, as opposed to a pump, and allows for the collection of breast ductal fluid from individual ductal orifices. The DucPrep device shares similar design, material and operating characteristics as the Diagnostic, Inc. Breast Aspirator and nonpowered breast pumps. The subject device and these two predicate devices (i.e., the Diagnostic, Inc. Breast Aspirator and nonpowered breast pumps) are comprised of polymer cups which are placed over the breast nipple and are used in conjunction with a nonpowered mechanism for applying a gentle vacuum enabling fluid expression.

Data Supporting Substantial Equivalence
WHT conducted laboratory and clinical testing to demonstrate the safe and effective use of the WHT Device. Laboratory testing was conducted to evaluate specific device performance parameters. Clinical testing was conducted to evaluate human use of the device in human

subjects. This testing supported that use of the Windy Hill Technology DucPrep Breast Aspirator 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

DEC 23 1999

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

Re: K993342
Trade Name: DucPrep™ Breast Aspirator
Regulatory Class: II
Product Code: KNW
Dated: October 4, 1999
Received: October 5, 1999

Dear Ms. Soito:

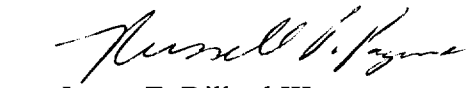
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for James E. Dillard III
Acting 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): K993342

Device Name: Windy Hill Technology DucPrep™ Breast Aspirator

Indications for Use:

The DucPrep Breast Aspirator device is used to elicit fluid from multiple ductal orifices for subsequent cytological evaluation and/or to identify ductal orifices for subsequent cannulation with the WHT Fuji Catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell L. Payne for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993342

Prescription Use X
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)