10. 510(k) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Noble Fiber Technology, Inc.
421 South State Street
Clarks Summit, PA 18411

Contact Person and telephone number:

William McNally, President
Telephone: 877-978-2842
Telefax: 877-978-2842

Date Summary was Prepared

December 5, 2003, Revised January 6, 2005

10.1.2 Name of Device

Trade Name:	X-Static® SILVERSEAL™ Hydrocolloid Film and Island Dressing
Common Name:	Silver-nylon Hydrocolloid Film and Island Dressing
Classification Name:	Hydrocolloid Film and Island Dressing

10.1.3 Identification of predicate device to which substantial equivalence is being claimed

X-Static® SILVERSEAL™ Hydrocolloid Film and Island Dressings are substantially equivalent in function and intended use to the following cleared Hydrocolloid Film and Island Dressings: Arglaes Film Dressing (K990810, Maersk Medical, Ltd.), Acticoat™ 7 Dressing (K001519, Westaim Technologies, Inc.), Tegapore™ Hydrocolloid Dressing (K982893, 3M Health Care), Hydrocolloid & Intelligent Hydrocolloid Wound Dressing (K983303, Innovative Technologies, Limited), and Contreet Hydrocolloid Dressing (K013525, Coloplast Corporation).

10.1.4 Device Description

Explanation of how the device functions: X-Static® SILVERSEAL™ Hydrocolloid Film and Island Dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. Laboratory antibacterial testing has demonstrated that the silver provides effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device: The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in X-Static®

SILVERSEAL™ Hydrocolloid Film and Island Dressing consists of a thin layer of metallic silver containing approximately 1.5% of 99% elemental silver that provides effective protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: Physical Description: 4 ¼ x 4 ¼ OD with a 2.5" x 2.0" square silver-colloid pad. The pad will consist of a colloid-film laminate, laminated to X-Static silver-plated nylon, number 90203.

10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended

X-Static® SILVERSEAL™ Hydrocolloid Film and Island Dressings indicated for: partial and full thickness dermal ulcers, leg ulcers (vascular, venous, pressure and diabetic), superficial wounds, abrasions, first and second degree burns, and donor sites.

10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

The technological characteristics of the device are substantially equivalent to the technological characteristics as the predicate devices cited.

10.2 **Assessment of Performance Data**

X-Static® SILVERSEAL™ Hydrocolloid Film and Island Dressings were subjected to standard tests including cytotoxicity, sensitization, acute intracutaneous reactivity, acute systemic toxicity, and tissue compatibility (muscle implantation study). All in vitro tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North American Science Associates, Inc. (NAMSA). All claims are the result of In Vitro studies and that the effect of the antibiotic has not been studied in a clinical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Ms. Patricia Davidson
Director of Legal Affairs
Noble Fiber Technologies
421 S. State Street
Clarks Summit, Pennsylvania 18411

Re: K033900
Trade/Device Name: X-Static Silverseal Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 11, 2004
Received: November 12, 2004

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K033900

Device Name: X-STATIC SILVERSEAL HYDROCOLLOID DRESSING

Indications For Use: **X-Static Silverseal Hydrocolloid Film and Island Dressings are indicated for: partial and full thickness dermal ulcers, leg ulcers (vascular, venous, pressure and diabetic), superficial wounds, abrasions, first and second degree burns, and donor sites.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033900