9. 510(k) SUMMARY

9.1 Summary Information

9.1.1 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

June 17, 2005

9.1.2 Name of Device

Trade Name:	SILVERSEAL® Orthotic Component With X-Static®
Common Name:	Limb Orthosis Stockinette Orthotic Applicance Stockinette Cervical Collar Stockinette
Classification Name:	ISH

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

SILVERSEAL™ Orthotic Component with X-Static® is substantially equivalent to SILVERSEAL® Tubular Cast Component with X-Static® (K043526, Noble Fiber Technologies, Inc.), with respect to the function, intended use and composition of the knitted stockinette.

9.1.4 Device Description

Explanation of how the device functions: SILVERSEAL® Orthotic Components with X-Static® are designed to externally contact the skin.

Basic scientific concepts that form the basis for the device: The surface of the nylon fibers in SILVERSEAL® Orthotic Component with X-Static® consists of a thin layer of metallic silver containing approximately 1.5% silver oxide that provides effective protection against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: SILVERSEAL® Orthotic Components with X-Static® are made of flexible, non-adherent fabric consisting of a knitted or spun nylon fabric which is 90% cotton or polyester, and 10% of a

continuous nylon fiber substrate with a metallic silver surface containing approximately 1.5% silver oxide.

9.1.5 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

SILVERSEAL® Orthotic Components with X-Static® are used as components on various orthotic devices intended for medical purposes that can be worn as a cervical collar or brace. The component comprises a knitted stockinette which is made of 90% cotton or polyester, and 10% X-Static®, which is 1.5% silver oxide. The component provides the skin with an antimicrobial barrier.

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

The technological characteristics of the device, aids in the protection against microbial contamination of the skin that are substantially equivalent to the predicate devices cited.

9.2 Assessment of Performance Data

SILVERSEAL® Orthotic Components with X-Static® were subjected to standard in vivo biocompatibility tests including cytotoxicity, sensitization, and acute intracutaneous reactivity. All 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 have not been studied in a clinical setting. The studies indicated that SILVERSEAL® Orthotic Components with X-Static® are safe for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

Mr. William F. McNally
President
Noble Fiber Technologies Incorporated
421 South State Street
Clarks Summit, Pennsylvania 18411

Re: K051256
Trade/Device Name: Silverseal® Orthotic Components X-Static®
Regulation Number: 21 CFR 890.3420
Regulation Name: External limb prosthetic component
Regulatory Class: I
Product Code: ISH
Dated: May 12, 2005
Received: May 16, 2005

Dear Mr. McNally:

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

Enclosure

K051256

Indications for Use

510(k) Number (if known):

Device Name:___SILVERSEAL® ORTHOTIC COMPONENTS X-STATIC®

Indications For Use:

SILVERSEAL® Orthotic Components with X-Static® are used as components on various orthotic devices intended for medical purposes that can be worn as a cervical collar or brace. The component comprises a knitted stockinette which is made of 90% cotton or polyester, and 10% X-Static®, which is 1.5% silver oxide. The component provides the skin with an antimicrobial barrier.

Prescription Use _____ AND/OR Over-The-Counter Use ___x___
(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)

...on Sign-Off)
...ion of General, Re...rative
... Neurological Devi...
K051256