JUL 1 3 2007

K063805

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SECTION 5 - 510(K) SUMMARY

1. **Submitter of the Application:**

NUCRYST Pharmaceuticals, Inc.
50B Audubon Rd.
Wakefield, MA 01880

Contact Person:

Steven J. Chartier
NUCRYST Pharmaceuticals, Inc.
50B Audubon Rd.
Wakefield, MA 01880
781-992-6044 (tel)
781-246-6032 (fax)

2. **Proprietary Name:** Silcryst® Silver Antimicrobial Wound Cream

Common/Usual Name: Dressing, Wound &Burn,
Hydrogel w/Drug or Biologic

Classification Name: Dressing, Wound & Burn,
Hyrdrogel w/Drug or Biologic

3. **Substantially Equivalent Devices:**
NUCRYST Pharmaceuticals, Inc. believes that Silcryst® Silver Antimicrobial Wound Cream is substantially equivalent to the currently marketed devices, Bioderm Sciences Wound Cream cleared under K042352, Acryderm Silver Antimicrobial Wound Gel cleared under K011994, and Acticoat™ Antimicrobial Barrier Dressing cleared under K955453.

4. **Device Description:**
Silcryst® Silver Antimicrobial Wound Cream is a non-sterile, semi-viscous emulsion intended for topical application for external wound management. It aids the body by providing a moist wound environment optimal for healing. The cream also serves as a broad spectrum anti-microbial barrier. It is presented as a prescription product.

5. **Intended Use of the Device:**
Silcryst® Silver Antimicrobial Wound Cream is intended for external management of partial and full-thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, cuts, donor sites and surgical wounds. It can be used in conjunction with a conventional dressing that absorbs fluids.

6. **Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):**
All products referenced are wound care products that are applied topically to externally manage the treatment of various wounds.

7. **Tests and Conclusions:**
Functional and performance testing has been conducted to assess the safety and efficacy of Silcryst® Silver Antimicrobial Wound Cream and results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

NUCRYST Pharmaceuticals, Inc.
% Mr. Steven J. Chartier
Sr. Director, Preclinical Development
& Regulatory Affairs
50B Audubon Road
Wakefield, Massachusetts 01880

Re: K063805
Trade/Device Name: Silcryst™ Silver Antimicrobial Wound Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 28, 2007
Received: July 2, 2007

Dear Mr. Chartier:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

Silcryst™ Silver Antimicrobial Wound Cream

510(k) Number: K063805

Device Name: Silcryst™ Silver Antimicrobial Wound Cream

Indications for Use:

Silcryst® Silver Antimicrobial Wound Cream is intended for external management of partial and full-thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, cuts, donor sites and surgical wounds.

√ Prescription (Per 21 CFR 801.109)	or	Over the Counter Use (Optional Format 1-2-96)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063805