

## 510(K) Summary

Pursuant to Section 12 Part (a) (i) 3A of the Safe Medical Devices Act of 1990 Quinnova Pharmaceuticals, Inc. is providing a summary of the safety and effectiveness information available for NEOSALUS Lotion as well as the substantial equivalence decision making process used for NEOSALUS Lotion.

### Sponsor/Applicant Name and Address:

Quinnova Pharmaceuticals, Inc.  
411 South State Street  
3<sup>rd</sup> Floor  
Newtown, PA 18940

JUL 30 2009

### Sponsor Contact Information:

Shahbaz Khan, M.D. - Associate Director  
Phone: 215-550-2005  
Fax: 215-860-8265  
e-mail: [skhan@quinnova.com](mailto:skhan@quinnova.com)

### Date of Preparation of 510(k) Summary:

May 18, 2009

### New Device Trade/Proprietary Name:

NEOSALUS Lotion

### Device Common/Classification Name:

Dressing. Wound and Burn. Hydrogel with Drug and/or Biologic

### Predicate Device/s Name and 510(k) Number/s:

NEOSALUS Cream (K090585)

### Device Description:

NEOSALUS Lotion is fragrance-free, water-soluble dressing formulated for the management and relief of irritation experienced with various types of dermatoses including atopic dermatitis and allergic contact dermatitis. NEOSALUS Lotion is intended for topical application.

### Intended Use:

NEOSALUS Lotion is a non-sterile formulation intended for topical application. It is intended for prescription use for the management of various types of dermatoses including atopic dermatitis and allergic contact dermatitis.

### Performance Data:

The predicate device referenced is non-sterile formulation that is applied topically to relieve the symptoms of various types of dermatoses.

### Conclusions:

Based on the 510(k) summaries (21CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Food Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 30 2009

Quinnova Pharmaceuticals  
% Shahbaz Khan, M.D.  
Associate Director  
411 S. State Street, 3rd Floor  
Newton, Pennsylvania 18940

Re: K091719  
Trade/Device Name: NEOSALUS Lotion  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: May 28, 2009  
Received: June 11, 2009

Dear Dr. Khan:

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 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.

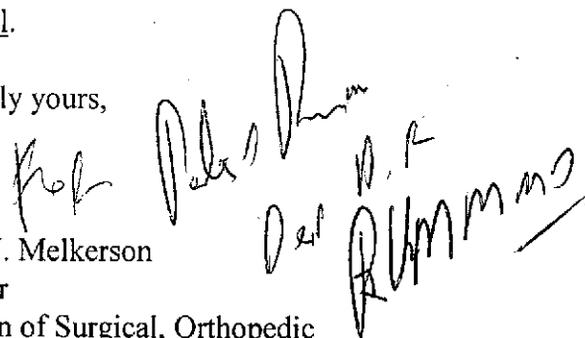
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Handwritten signature of Mark N. Melkerson in black ink, appearing as 'Mark N. Melkerson' with a stylized flourish.

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

Enclosure

**Indications for use**

**510(k) Number (if known):** K091719  
N. A.

**Device Name:**

NEOSALUS Lotion

**Indications for Use:**

NEOSALUS Lotion is indicated for management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

**Prescription Use**  **(21 CFR 801 Subpart D)**

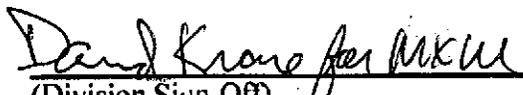
AND/OR

**Over-The-Counter Use**  **(21 CFR 801 Subpart C)**

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**Concurrence of CDRH-Office of Device Evaluation [ODE]**

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K091719