K042722

JAN 13 2005

Attachment 7
510(k) Summary

September 30, 2004

1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals, Ltd.
Address: Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: 1 972 478 4380
Contact Person: Michael Killeen, Executive Vice President, North America

2. Name of Device:	**ALOCLAIR™ ORAL SPRAY**
Trade/Proprietary/Model Name:	**ALOCLAIR™ ORAL SPRAY**
Common or Usual Name:	Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Names:	Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. Devices to Which New Device is Substantially Equivalent:

Sinclair Aloclair Oral Gel cleared in 510(k) K049050

Sinclair Aloclair Oral Rinse cleared in 510(k) K023155

4. Device Description:
ALOCLAIR™ ORAL SPRAY is a viscous spray formulation, which is presented for over-the-counter use premixed in various sizes. This combination of substances, when rinsed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

Aloclair™ Oral Spray is indicated for pain relief in all types of mouth lesions, aphthous stomatitis, aphthous ulcers, minor lesions, chafing and traumatic ulcers and abrasions caused by braces and ill fitting dentures and diffused aphthous ulcers. Aloclair Gel forms a protective film that covers lesions to provide rapid pain relief, and avoid further irritation.

K043732

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The ALOCLAIR™ ORAL SPRAY has the same intended/indications for use as the predicate Aloclair Oral Gel and Aloclair Rinse.

Product Name	*Aloclair Spray*	*Aloclair Gel*	*Aloclair Rinse*
Method of Use	Pre-mixed	Pre-mixed	Pre-mixed
# of applications per day	Take as needed	Take as needed	Take as needed
Claim	Management and relief of pain, non irritating, does not sting, safe if swallowed	Management and relief of pain, non irritating, does not sting, safe if swallowed	Management and relief of pain, non irritating, does not sting, safe if swallowed
Area of Use	Oral Mucosa	Oral Mucosa	Oral Mucosa
Disease State	Aphthous Ulcers Stomatitis, Oral lesions	Aphthous Ulcers Stomatitis, Oral lesions	Aphthous Ulcers Stomatitis, Oral lesions
Type of Product	Oral Gel Rinse/Mouthwash	Oral Gel Rinse/Mouthwash	Oral Rinse/Mouthwash
Presentation	Non Sterile	Non Sterile	Non Sterile

7. Tests and Conclusions:

Extensive functional and performance testing were conducted to assess the safety and effectiveness of Aloclair® ORAL SPRAY. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Michael Killeen
Executive Vice President
Sinclair Pharmaceuticals, Limited
Borough Road
Godalming, Surrey, GU7 2AB
UNITED KINGDOM

Re: K042722
Trade/Device Name: ALOCLAIR™ ORAL SPRAY
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: September 29, 2004
Received: October 29, 2004

Dear Mr. Killeen:

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.

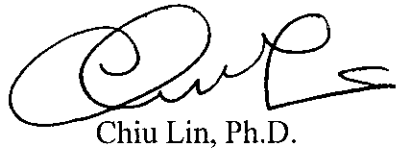
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-0115. 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/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use

510(k) Number (if known) K042722

Device Name ALOCLAIR™ ORAL SPRAY

Indications for Use

ALOCLAIR™ ORAL SPRAY is indicated for all types of mouth lesions, aphthous stomatitis, aphthous ulcers, minor lesions, chafing and traumatic ulcers caused by braces and ill fitting dentures and diffused aphthous ulcers.

Prescription Use _____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___√___ (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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K042722