K053166

Attachment 7

510(k) Summary

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1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals Limited
Address:
Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

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

2. Name of Device: **SINCLAIR ORAL RINSE**

Trade/Proprietary/Model Name: **SINCLAIR ORAL RINSE**
Common or Usual Name: Delmopinol hydrochloride
Classification Names:

3. Devices to Which New Device is Substantially Equivalent:
Decapinol Oral Rinse 510(k) K041482

4. Device Description:

SINCLAIR ORAL RINSE contains Delmopinol hydrochloride, an anti-plaque agent that presents a surface barrier preventing oral bacteria from adhering to and colonizing on tooth surfaces and forming dental plaque.
SINCLAIR ORAL RINSE helps prevent the binding of bacteria to the tooth surfaces, thereby interfering with the primary steps of plaque formation.

5. Intended Use of the Device:

SINCLAIR ORAL RINSE helps to prevent and reduce gingivitis, when used as directed.

SINCLAIR ORAL RINSE serves as an adjunct to normal mechanical oral hygiene where this has proved inadequate.

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

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SINCLAIR ORAL RINSE is substantially equivalent to the following devices:

Decapinol Oral Rinse cleared in 510(k) K041482, which is an oral rinse indicated for the relief and management of gingivitis. Sinclair Oral Rinse has the same intended use (oral rinse) as the predicate device, as required by 510(k) regulations.

Sinclair Oral Rinse has the same technological characteristics as the predicate, in that each oral rinse achieves their purpose as physical barrier, coating the oral mucosa and gingiva, thus reducing the adherence of colonizing bacteria.

Extensive in vitro and in vivo testing has documented the safety and efficacy of Sinclair Oral Rinse and documentation is enclosed.

In summary, the **SINCLAIR ORAL RINSE** described in this submission is, in our opinion, substantially equivalent to the predicate Decapinol Oral Rinse cleared in 510(k) K041482 by meeting the following standards set by FDA:

- has the same intended use as the predicate device; and
- has the same technological characteristics as the predicate device; or
- and the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

7. Tests and Conclusions:

Functional and performance testing has been conducted to assess the safety and effectiveness of **SINCLAIR ORAL RINSE**. A summary of the results is attached in Attachment 5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

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

Re: K053166
Trade/Device Name: Sinclair Oral Rinse
Regulation Number: 21 CFR 872.5580
Regulation Name: Oral Rinse
Regulatory Class: II
Product Code: NTO
Dated: May 3, 2006
Received: May 8, 2006

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.

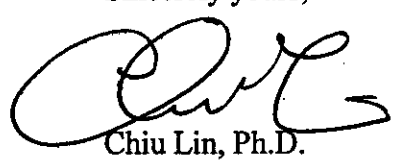
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

K053166

Attachment 3

Indications for Use Statement

510(k) Number
(if known)

Device Name **SINCLAIR ORAL RINSE**

Indications for Use

OTC labeling:

SINCLAIR ORAL RINSE helps to prevent and reduce gingivitis, when used as directed.

SINCLAIR ORAL RINSE serves as an adjunct to normal mechanical oral hygiene where this has proved inadequate.

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

Susan Runner

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

(510(k) Number: K053166