

SEP 2 1999

510(k) SUMMARY**SOOTHE-N-SEAL™ Canker Sore Relief****1. Device Name**

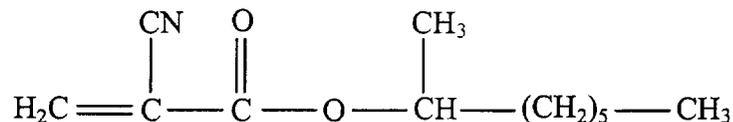
Trade Name: SOOTHE-N-SEAL™ Canker Sore Relief
 Common Name: Liquid Protectant for Canker Sore Pain Relief
 Classification Name: unclassified
 Predicate Devices: K902078, K980159 Octylident® Dental Adhesive
 K933741, K964852 Carrington® OraPatch™

2. Device Description

SOOTHE-N-SEAL™ Canker Sore Relief (formulated 2-octyl cyanoacrylate) is a non-sterile, clear, colorless, free-flowing liquid protectant packaged in high-density polyethylene multiple-use, controlled dropper bottles. The device package contains one gram of liquid protectant and 10 double-ended applicator swabs in a transparent polyethylene terephthalate tray with cardboard display label. Each end of the swab handle consists of a polyurethane foam sponge tip, one end rounded for drying the ulcer area and one end pointed for device application.

SOOTHE-N-SEAL™ Canker Sore Relief is composed of 2-octyl cyanoacrylate (>99%) with small amounts of polymerization inhibitors added to enhance shelf life. The chemical characteristics of 2-octyl cyanoacrylate are provided below.

Chemical name: 2-octyl cyanoacrylate
 CAS registry number: 133978-15-1
 Molecular formula: C₁₂H₁₉NO₂
 Molecular weight (g/mole): 209
 Structural formula:

**3. Intended Use**

SOOTHE-N-SEAL™ Canker Sore Relief creates a thin, protective barrier that provides immediate and long lasting relief of pain associated with canker sores, mouth sores, and traumatic ulcers, such as those caused by braces.

4. Summary of Technological Characteristics

When applied on tissue surfaces of the mouth, the liquid formulation polymerizes to form a thin, protective film, typically within five seconds. Once polymerized, the applied layer of 2-octyl cyanoacrylate has a high degree of adhesion strength and flexibility. The polymer film is crenated and has a slightly rough feel in the mouth. The film remains adhered to the tissue surface until the underlying tissue to which it is bonded is spontaneously sloughed through natural re-epithelialization or until mechanically displaced.

5. Summary of Clinical Performance Data

The safety and effectiveness of SOOTHE-N-SEAL™ Canker Sore Relief in the management of oral ulcers has been demonstrated through two clinical studies. The first study was a single-center study of 42 subjects who were randomized to treatment with one of two device formulations or to sham treatment using saline. In this study, the device was applied by the clinical investigator twice on the day of enrollment, then once a day for the next three days, for a total of five applications. The second clinical study was a multi-center clinical study of 155 subjects who were randomized to receive either SOOTHE-N-SEAL™ Canker Sore Relief, a predicate device (the Carrington® OraPatch™), or a negative control (water). In this study, the device was self-applied by the study subjects four times a day according to labeled directions until the resolution of ulcer pain.

During the enrollment visit, subjects in both studies recorded unchallenged, or ambient, pain and challenged pain in response to holding an irritant, orange juice, in contact with the oral ulcer. These pain assessments were performed to measure the pain reduction provided by a single device application. Subjects in both studies also recorded unchallenged pain four times daily in a study diary and were examined daily by the clinical investigator until ulcer healing.

5.1 Device Safety

Results of the clinical evaluation of SOOTHE-N-SEAL™ Canker Sore Relief show the device may be safely used for the management of oral ulcers. No significant adverse effects are associated with use of SOOTHE-N-SEAL™ Canker Sore Relief and no significant concerns are associated with the application technique to successfully apply a protective film in a single application. There is also no evidence from the multi-center study that use of the device up to four times daily has any adverse effects on healing or resolution of ulcer pain.

5.2 Pain Reduction

Outcomes of both clinical studies show that one application of SOOTHE-N-SEAL™ Canker Sore Relief significantly reduces pain immediately after application as measured by a standardized challenge when compared to sham treatment. All subjects randomized to SOOTHE-N-SEAL™ Canker Sore Relief in the multi-center study were able to place the protective film correctly in a single application on the first attempt. This indicates that the device is effective in its ability to be used by the subject to create a protective barrier over the ulcer when the subject is provided with the labeled instructions. Results show that this immediate pain reduction is equal to that achieved by the predicate device, the Carrington® OraPatch™.

Long term pain reduction was also demonstrated after one application of SOOTHE-N-SEAL™ Canker Sore Relief in the multi-center study. Of the subjects in this group initially reporting a reduction in challenged pain (76%), nearly half continued to record a reduction in pain over four hours later, prior to the second application of the device. This was better than the performance of the predicate device, the Carrington® OraPatch™, which performed more closely to sham in this analysis.

The total pain experienced over the ulcer episode and the time to total relief of ulcer pain were not significantly different between subjects randomized to SOOTHE-N-SEAL™ Canker Sore Relief and those randomized to the other arms of the multi-center study.

5.3 Ulcer Healing

The results of the two clinical studies performed for SOOTHE-N-SEAL Canker Sore Relief indicate that use of the device may benefit ulcer healing and is not detrimental to healing when self-applied by the subject up to four times a day.

5.4 Conclusions Regarding Clinical Performance Data

Clinical studies verify that SOOTHE-N-SEAL™ Canker Sore Relief, when used in an over-the-counter environment, performs safely and as intended to reduce the pain of oral ulcers. Clinical study users considered the product to be effective and easy to use compared to other canker sore products currently available. Overall results show that SOOTHE-N-SEAL™ Canker Sore Relief is safe and appropriate for consumer use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. W. Thomas Stephens
Manager, Regulatory Affairs
Closure Medical, Corporation
5250 Greens Dairy Road
Raleigh, North Carolina 27616

Re: K991923

Trade Name: Soothe-N-Seal™ Canker Sore Relief
Regulatory Class: II
Product Code: MZW
Dated: June 4, 1999
Received: June 7, 1999

Dear Mr. Stephens:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

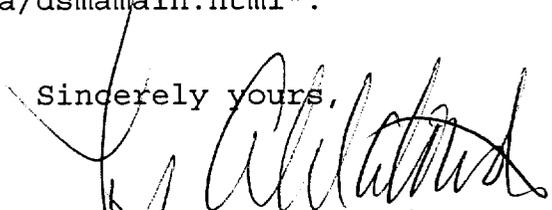
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991923 SOOTHE-N-SEAL™ Canker Sore Relief

STATEMENT OF INDICATIONS FOR USE

Device Name: SOOTHE-N-SEAL™ Canker Sore Relief

Indications For Use:

SOOTHE-N-SEAL™ Canker Sore Relief creates a thin, protective barrier that provides relief of pain associated with canker sores, mouth sores, and traumatic ulcers, such as those caused by braces.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

(Optional Format 1-2-96)

Susan Puras
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991923