K012126

OCT - 3 2001

510 (k) SUMMARY

The SaliCept™ Oral Patch

The following represents the summary for premarket notification of The SaliCept Oral Patch, a product to be marketed by Carrington Laboratories, Inc., located at 2001 Walnut Hill Lane, Irving, TX 75038, (972) 518-1300.

CONTACT PERSON: Kenneth M. Yates, D.V.M.
Vice President, Research and Development/Regulatory Affairs
(972) 650-7312

DEVICE OR PROPRIETARY NAME: The SaliCept™ Oral Patch

CLASSIFICATION NAME: Hydrogel Wound Dressing

COMMON NAME: Hydrogel Wound Dressing

ESTABLISHMENT REGISTRATION NUMBER: 16125446

DATE OF SUMMARY: June 19, 2001

CLASSIFICATION OF THE DEVICE:
Unclassified under 21 CFR 8728.4022, hydrogel wound dressing and burn dressing. The predicate device, K953423, The Carrington™ Patch, is an unclassified device.

DEVICE DESCRIPTION:
The SaliCept Oral Patch is a freeze-dried gel that contains Acemannan Hydrogel,™ a product obtained from the clear inner gel of *Aloe vera* L. Other ingredients include hydroxyethyl cellulose, polyvinylpyrrolidone, benzethonium chloride, simethicone. It is pliable, white to off-white, with a texture similar to that of finely woven cotton. The SaliCept Oral Patch is packaged in blister cards of six pledgets per card, two blister cards per carton, for a total of 12 pledgets per carton. Each pledget is approximately 1 cm in diameter and 0.5 cm thick.

INTENDED USE:
The SaliCept Oral Patch is recommended for use in extraction sites and management of alveolar osteitis (dry socket). The SaliCept Oral Patch is also intended for the management of all types of wounds, injuries and ulcers of the oral mucosa. It is intended for professional use only, and will be marketed to dentists and other health professionals.

CLAIMS:
The SaliCept Oral Patch relieves pain by adhering to and protecting affected tissues from further irritation. It is safe if swallowed.

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TECHNOLOGICAL CHARACTERISTICS:
The SaliCept Oral Patch is a freeze-dried hydrogel that adheres to oral mucosa. It slowly reverts to the gel state in the oral environment while it adheres to and protects tissues.

NON-CLINICAL DATA:
An *in vitro* study was conducted in which both cultured human buccal mucosal scrapings and cultured human gingival fibroblasts were exposed to Acemannan Hydrogel that had been labeled with fluorescein-5-isothiocyanate I (FITC). A high affinity of FITC-labeled Acemannan Hydrogel for both cell cultures was demonstrated, whereas FITC alone did not appreciably stain either cell type. Of significance was the finding that FITC-labeled Acemannan Hydrogel had a high affinity for keratin.

CLINICAL DATA:
Thirty-seven patients with oral aphthous ulcers applied either Orabase-Plain or the SaliCept Oral Patch to their lesions. Both groups experienced significant reduction in pain within 20 minutes, with the pain relief lasting longer than the 1-hour observation period (Plemons J, Rees T, Binnie W, Wright J: Pain relief evaluation of Carrasyn® Hydrogel for recurrent aphthous stomatitis. Abstract presentation, 73rd General Session and Exhibition of the International Association for Dental Research, Singapore, 1995).

A clinical trial in which 90 patients with oral aphthous ulcers was conducted. Patients applied either Orabase-Plain, Carrington's Carrasyn Hydrogel Dressing in gel form, or Carrington's SaliCept Oral Patch to their ulcers. The SaliCept Oral Patch group experienced significant reduction in pain within 2 minutes of application (Plemons JM, Rees TD, Binnie WH, Wright JM, Guo I, Hall, JE: Evaluation of acemannan in the treatment of recurrent aphthous stomatitis. *Wounds* 1994;6(2):40-45).

A clinical trial compared reduction in discomfort in 155 patients with oral aphthous ulcers. Patients applied either the SaliCept Oral Patch, a cyanoacrylate bioadhesive, or a negative control to their lesions. Both the SaliCept Oral Patch group and the cyanoacrylate bioadhesive group experienced significant reduction in pain vs negative control. There was no difference in pain reduction between the two active groups.

A clinical trial compared the incidence of alveolar osteitis (AO, dry socket) in tooth extraction sites in which either clindamycin-soaked Gelfoam or the SaliCept Oral Patch was immediately placed post-extraction. Analysis revealed that 78 of 975 (8.0%) of mandibular 3rd molar sites in the Gelfoam group developed AO whereas 11 of 958 (1.1%) mandibular 3rd molar sites developed AO in the SaliCept Oral Patch group. When all extraction sites were analyzed, it was shown that 78 of 1031 (7.6%) extraction sites in the Gelfoam group developed AO whereas 12 of 1064 (1.1%) extraction sites developed AO in the SaliCept Oral Patch group. The difference between groups was significant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. Kenneth M. Yates
Vice President, Research and Development
Carrington Laboratories, Incorporated
2001 Walnut Hill Lane
Irving, Texas, 75038

Re: K012126
Trade/Device Name: The SaliCept™ Oral Patch
Regulation Number: None
Regulation Name: Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: June 19, 2001
Received: July 6, 2001

Dear Mr. Yates:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

510(k) Number: K012126

Device Name: The SaliCept™ Oral Patch

Indications for Use:
Recommended for use in tooth extraction sites and management of alveolar osteitis (dry socket). The SaliCept Oral Patch is also intended for the management of all types of oral wounds, injuries and ulcers of the oral mucosa. The Salicept Oral Patch relieves pain by adhering to and protecting affected tissues from further irritation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012126