K101771

Majestic Drug Inc.
Reline-It™ 510(k) Summary

Date Prepared [21CFR 807.92(a)(1)]
June 18, 2010

Submitter's Information [21CFR 807.92(a)(1)]

Sponsor:

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SEP 20 2010

The establishment registration number for Majestic Drug Inc. is 2411564

Contact Information:

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Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:

Reline-It™

Device common, usual or Classification Names

Device: Reliner, denture, over the counter

Regulation Description: OTC Denture Reliner

Class

Classification: Class II
Product Code: EBP, 21 CFR 872.3560

The subject device is packaged with the following items:

- Container of clear polymer powder
- Container of liquid monomer
- Mixing/Application Spatula
- Mixing Tray
- Instructions for Use

Intended Use [21 CFR 807.92(a)(5)]

The device has the following "Indications for Use":

- For over the counter temporary replacement of soft denture lining until a Dentist can be seen.

Technological Characteristics [21 CFR 807.92(a)(6)]

Majestic Drug Inc. maintains that the subject device is substantially equivalent to the predicate devices in that they all are similar in technology, function and intended use.

Labels, Labeling

Per section "Labels and Instruction For Use"

Performance Data [21 CFR 807.92(b)(1)]

Articles and supporting documents are included in sections "Conformance to Voluntary Standards" and "Clinical and Scientific Studies"

Predicate Devices [21 CFR 807.92(a)(3)(1)]

- DEN – MAT CORP "DENTURE-TIGHT" K790589
- LEE PHARMACEUTICALS "ACRYLINE 2"(510(k) unknown)
- PERMA LABORATORIES PERMA SOFT II. (510(k) unknown)

The subject device is substantially equivalent (materials, technology) to the above listed devices.

Device Description [21 CFR 807.92(a)(4)]

The subject device is a temporary OTC soft, clear denture reliner consisting of 2 parts (1) a monomer liquid and (2) a polymer powder which are mixed together prior to application. This results in a plastic resin paste which is then applied to the denture plate and set in the mouth to cure for a short period of time. Once setting is complete, the excess soft material is able to be trimmed by an enclosed spatula. The application is completely reversible by soaking the denture plate overnight in an over the counter solution of hydrogen peroxide and then removing it by hand. The material contains no Methyl Methacrylate Monomer, no Phthalate Plasticizer, no Bisphenol A, no leachable alcohol and no Cadmium colors.

The subject device is similar to the device that was cleared under premarket submission to DEN – MAT CORP K790589 DENTURE-TIGHT, LEE PHARMACEUTICALS "ACRYLINE 2" a currently available OTC denture reliner and PERMA LABORATORIES PERMA SOFT II which is also marketed on the internet as an OTC product.

Background:

The purpose of this submission is to follow the Food and Drug Administrations' Guidance document issued Aug 18, 1998 "*OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits,*" along with verbal technical guidance from FDA technical contacts to present a successful representation of the subject device to obtain an OTC marketing clearance by the FDA.

There is some confusion on the present availability of technical information on 3 existing marketed devices; (1) Den-Mat's "Denture-Tight" K790589 obtained clearance, however technical data on formulation and a marketed sample was not available from present research efforts, and (2) Lee Pharmaceuticals "Acryline 2" is presently available on the internet, however a 510(k) could not be found for the device. (3) In addition, the FDA database did have one other device listed under product code EBP. The device name is "PERMA SOFT II, manufactured by PERMA LABORATORIES. This device is currently marketed on the internet, however a 510(k) could not be found. Given these circumstances, a recent telephone conversation with a technical contact at the FDA indicated that a successful clearance could be obtained by demonstrating conformance to the above referenced document "*OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits*", and by clearly stating all warnings and precautions in the instructions for use and labeling. Each of these devices along with the subject device, "Reline-It™" are soft, removable over the counter denture reliners. The chemistry, methods of application and intended use are essentially identical.

The information in this submission will clearly detail the formulation, safety and effectiveness data of the subject device without the benefit of having technical information of the devices listed above and all similar pre amendment devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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C/O Mr. Roger S. Mastrony
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848-1/2 Derby Avenue
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SEP 20 2010

Re: K101771
Trade/Device Name: Reline-It
Regulation Number: 21 CFR 872.3560
Regulation Name: OTC Denture Reliner
Regulatory Class: II
Product Code: EBP
Dated: June 24, 2010
Received: June 24, 2010

Dear Mr. Mastrony:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

"INDICATIONS FOR USE"
Statement

SEP 2 0 2010

510(k) Number (if known): **K101771**

Device Name: Reline-It

The Device has the following "Indications for Use":

An over the counter temporary Denture Reliner, intended to replace a worn denture lining.

Prescription Use____ OR Over-The Counter Use _X_
(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner (Optional Format 1-2-96)

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

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