K121318

Attachment 2

JUN - 6 2012

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Contact name: Melissa Lima
PERMA LABORATORIES
120 Wakefield Run Blvd.
Hinckley, OH 44233
Phone: 800-988-9194
Registration No.: 1528710

Date Prepared: April 2, 2012

2. **Name of the Device:** ProSoft™

3. **Common or Usual Name and Classification:**

Common Name: OTC Denture Reliner Kit
Regulation: 21CFR Part 872.3560
Product Code: EBP

4. **Predicate Device Information**:

RELINE-IT was cleared under k101771.
Tempo Tissue Conditional Reliner was cleared under k081514.

5. **Device Description** :

ProSoft™ is an over the counter temporary Denture Reliner kit. The device contains a Polyethyl Methacrylate powder, a liquid Ethyl Alcohol, and a mixing stick. The material contains no Methyl Methacrylate Monomer, no Phtalate Plasticizer, no Bisphenol A, and no Cadmium colors.

The powder and the liquid are to be mixed together with the mixing stick to make the relining material. The relining material is then poured into the denture base and placed into the mouth to make the impression.

Once the impression has cured any excess material is trimmed with a sharp knife.

Can be easily removed with warm water or soaking in a solution of hydrogen peroxide and water overnight.

6. **Intended Use**

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

7. **Comparison to Predicate Devices:**

The ProSoft™ is substantially equivalent to the RELINE-IT in intended use, operation, safety and function.

The subject device is a self-curing reliner, whereas, the predicate device cures by placing the relined denture in hot water for 20 minutes. After following instructions for both relines the same results are achieved. Both devices form a soft, temporary denture base to relieve loose, irritating dentures resulting in substantial equivalence in regards to safety and effectiveness.

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Bench testing was performed to assess the functionality of the device as outlined in the FDA Guidance Document "OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits". Comparative testing data was provided for the RELINE-IT device. Testing was performed by a third party laboratory.

Supporting documentation to demonstrate biocompatibility was also supplied as part of the 510(k) submission.

Analysis of the data showed that the devices are substantially equivalent.

9. **Discussion of Clinical Tests Performed:**

Clinical testing was not conducted.

10. Conclusions:

Based on the information provided in this submission we conclude that the ProSoft™ is substantially equivalent to the predicate and is safe and effective for its intended use.

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

Perma Laboratories
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

JUN - 6 2012

Re: K121318
Trade/Device Name: ProSoft Denture Reliner
Regulation Number: 21 CFR 872.3560
Regulation Name: OTC denture reliner
Regulatory Class: II
Product Code: EBP
Dated: May 22, 2012
Received: May 23, 2012

Dear Mr. Job:

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,

for

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
Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): K121318

Device Name: ProSoft Denture Reliner

Indications For Use:

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

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

Over-The Counter Use X (21 CFR 801 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: K121318