K994357

MAR 14 2000

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Regulatory & Marketing Services, Inc. (RMS)
3234 Ella Lane
New Port Richey, FL 34655

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary: November 26, 1999

Trade Name: BITEM LOCK

Classification Name: Orthodontic Appliance or Accessory

Predicate Device: K900678 Myloc System Winder Research

Device Description/ Comparison: The BITEM LOCK product is a thermo-adjustable alignment bracket with the same use as the predicate device. The only difference is the predicate device is Made from metal and this device is a thermo-adjustable material.

Intended Use: For use as an alignment bracket for removable dentures, and to aid in securing dentures.

K994357

510(K) Summary
Differences and Similarities

The BITEM LOCK product is fundamentally similar to the predicate device.

Intended Use:

Both BITEM LOCK and the predicate device have the same intended use.

Applications:

Both products are used in the same dental applications and are used within the same type of dental facility.

Technological Characteristics:

These products are different in material compounds and method of preparation and application with the clinician. The base materials for the BITEM LOCK include a methacrylate liquid, a phthalate plasticizer, an EGDMA cross linker and polymer powder. They are ready made for clinical application. The predicate device is aluminum and is secured by a spring sleeve and beading wax . The BITEM LOCK is secured with either a self or heat cure thermo-elastic acrylic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

ThermoElastic Technologies, Incorporated
C/O Mr. Art J. Ward
Medical Device Consultant
Regulatory and Marketing Services, Incorporated (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Re: K994357
Trade Name: BITEM LOCK, Models SW006, SW012
Regulatory Class: I
Product Code: EJF
Dated: December 1, 1999
Received: December 27, 1999

Dear Mr. Ward:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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" (21 CFR 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/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 (if known): _____

Device Name: ThermoElastic Technologies Inc.- BITEM LOCKS

Indications For Use:

Intended for Use as an aligning bracket for removable dentures, and to aid in securing dentures.

(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 _____
(Per 21 CFR 801.109)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994337

(Optional Format 1-2-96)