

JUN 23 1999

K991478

510(k) SUMMARY

Submitter's Data:

Capital Marketing Technologies, inc.
3630 South Interstate 35, Suite A
Waco, Texas 76706
Telephone: 1-800-887-3370 or (254) 662-1752
Fax: (254) 662-1760.
Contact person(s): John Snyder or Vonna Muesse
Date prepared: November, 1998

State of intended use:

TENDER TOUCH™ Silicone Gel Pads are designed to be worn on the body to help reduce pressure and friction against bony prominences, and they can also be used as scar management. This is not a wound covering or dressing and is not sterile.

Device Description:

TENDER TOUCH™ Silicone Gel Pads are soft silicone gel sheets that are applied over bony prominences. The sheets are not made of medical grade silicone and are not sterile. The sheets are square and rectangular and come in three sizes, 9cm x 9 cm, 6 cm x 6 cm and 3.5 cm x 6 cm. They are approximately .125 of an inch thick. The customers will determine which size sheet is best for their own application. The pad helps reduce friction and pressure against the skin. They can also be used as scar management.

The sheets are not for use on an open wound, are not sterile but can be washed. They can be used under casting and splints and can be cut to other shapes if necessary.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

Mr. John Snyder
Capital Marketing Technologies, Inc.
3630 South I 35, Suite A
Waco, Texas 76706

Re: K991478
Trade Name: Tender Touch™ Silicone Gel Pads
Regulatory Class: Unclassified
Product Code: MDA and FMP
Dated: April 21, 1999
Received: April 28, 1999

Dear Mr. Snyder:

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.

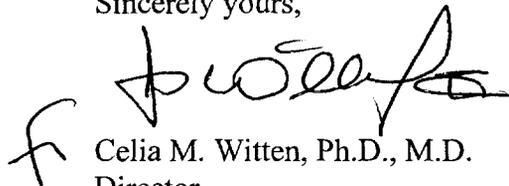
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. John Snyder

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a large, stylized letter "F".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991478

Page 1 of 1

510(k) Number (if known): 991478

Device Name: TENDER TOUCH TM SILICONE GEL PADS

Indications For Use:

TENDER TOUCH™ Silicone Gel Pads are designed to be worn on the body to help reduce pressure and friction against bony prominences, and they can also be used as scar management. This is not a wound covering or dressing and is not sterile.

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

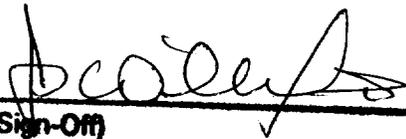
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991478