

K071710

5.0 510(k) SUMMARY

AUG 14 2007

Date Prepared: August 6, 2007

Applicant: Johnson & Johnson Consumer Products Company,
Division of Johnson & Johnson Consumer Companies, Inc.
201 Tabor Rd.
Morris Plains, NJ 07950
Telephone: 973-385-4619
Fax: 973-385-4300

Contact Person: Dagmar Oette, MD, JD
Director, Global Regulatory Affairs

Proprietary Name: BENGAY™ Heat Therapy
Common Name: Heat Patch/Pad/Wrap; Air-Activated Heat Patch/Pad/Wrap;
Pain Relieving Heat Patch/Pad/Wrap
Classification Name: Pack, Hot or Cold, Disposable
Product Code: IMD

Predicate Device: ThermaCare® Heat Wrap (various)
K953442
Procter & Gamble Co.
1 Procter & Gamble Plaza
Cincinnati, OH 45202

Description: BENGAY™ Heat Therapy is a disposable, single-use, air-activated pain relieving patch which adheres to the skin by means of a hydrogel adhesive and generates heat by the oxidation of iron powder.

Intended Use: Is intended for over-the-counter (non-prescription) use by the consumer.

Provides moist heat therapy to temporarily relieve minor muscle and joint aches and pain associated with over-exertion, strains, sprains, arthritis, stiffness, and muscle spasm.

Temporarily relieves minor menstrual pain.

Temporarily increases local blood circulation.

Technological
Characteristics:

The device consists of 6 components:

- Oxygen-impermeable, primary packaging;
- Breathable fabric sachet containing the heating element mixture;
- Heating element mixture;
- Backing sheet which separates the heating element mixture from the hydrogel layer;
- Hydrogel layer to provide adhesion to the skin surface; and,
- Release liner to protect the adhesive hydrogel layer prior to consumer use

When the air-tight, protective packaging is opened, the heating element mixture reacts with oxygen in the air, and the patch begins to warm up. It takes up to 30 minutes for the patch to reach its target temperature range. The patch stays warm for at least 8 hours.

Performance Data:

BENGAY™ Heat Therapy reaches its target temperature range in 30 minutes or less, and remains in this temperature range for a minimum of 8 hours.

BENGAY™ Heat Therapy provides moist heat as demonstrated by user perception and laboratory experiments.

The safety (potential for cumulative irritation and thermal-related injury; and, change in skin surface temperature) of BENGAY™ Heat Therapy was demonstrated in a clinical study that compared BENGAY™ Heat Therapy with the predicate device.

Biocompatibility Testing:

Based on the results of relevant biocompatibility testing (*in vitro* cytotoxicity; sensitization; and, dermal irritation studies), the final product is safe for use as a body contact surface medical device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2007

Johnson & Johnson
Consumer Products, Inc.
% Dagmar Oette, MD, JD
Director, Global Regulatory Affairs
201 Tabor Road
Morris Plains, New Jersey 07950

Re: K071710
Trade/Device Name: BENGAY® Heat Therapy
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: Class I
Product Code: IMD
Dated: June 20, 2007
Received: June 22, 2007

Dear Dr. Oette:

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.

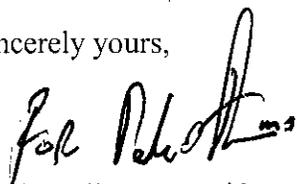
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark Melkerson *MS* *8/2/07*
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K071710

Device Name: BENGAY™ Heat Therapy

Indications for Use: Is intended for over-the-counter (non-prescription) use by the consumer.

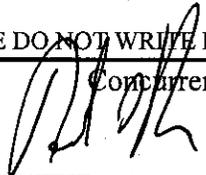
Provides moist heat therapy to temporarily relieve minor muscle and joint aches and pain associated with over-exertion, strains, sprains, arthritis, stiffness, and muscle spasm.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071710

Prescription Use _____
(Per 21 CFR §801.109)

OR

Over-the-Counter Use X