K121898

510(k) Summary
for the
Quick-Med Technologies, Inc.
Stay Fresh Skin Fold Management Textile

MAY 2 4 2013

1. SUBMITTER/510(K) HOLDER

Quick-Med Technologies, Inc.
902 NW 4th Street
Gainesville, FL 32601
352-379-0611
352-379-1099 (fax)

Contact Person: Susan Leander
Telephone: 352-379-0611

Date Prepared: May 24, 2013

2. DEVICE NAME

Proprietary Name:	*Stay Fresh*™ Skin Fold Management Textile
Common/Usual Name:	Skin Protectant
Classification Name:	Medical absorbent fiber
Classification Regulation:	21 CFR 880.5300
Product Code:	FRL

3. PREDICATE DEVICES

- Milliken Interdry Textile with Silver subject of K110715, K061615
- ConvaTec SurePress® Absorbent Padding which is listed with the FDA by Convatec

4. DEVICE DESCRIPTION

Stay Fresh Skin Fold Management Textile is a non-sterile skin protectant indicated for management of skin folds and other skin-to-skin contact areas, such as extremities, and is offered as a 25.4 cm x 365.8 cm fabric piece (other sizes may also be available). The device provides moisture management to keep skin dry and the device's low coefficient of friction reduces skin-to-skin friction. *Stay Fresh* Skin Fold Management Textile is a single patient use product that is custom cut from a multiuse package. Polyester fabrics are well known to wick moisture away from skin as well as provide a low friction surface.

5. INTENDED USE

The Stay Fresh Skin Fold Management Textile is a skin protectant intended to be used between skin folds and in other skin-to-skin contact areas to provide moisture management and reduce friction. The Stay Fresh Skin Fold Management Textile contains hydrogen peroxide, which reduces bacterial populations in the fabric.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The *Stay Fresh* Skin Fold Management Textile is substantially equivalent to the predicate devices with respect to material composition, device characteristics and intended use.

7. PERFORMANCE TESTING

The *Stay Fresh* Skin Fold Management Textile has been subjected to extensive testing to assess the biocompatibility and the performance of the device. The *Stay Fresh* Skin Fold Management Textile was shown to provide moisture management and antimicrobial properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 24, 2013

Quick-Med Technologies, Incorporated
Ms. Susan E. Leander, M.S.
Regulatory Affairs Coordinator
902 North West, 4th Street
GAINESVILLE, FL 32601

Re: K121898
Trade/Device Name: *Stay Fresh* Skin Fold Management Textile (SFMT)
Regulation Number: 21 CFR 880.5300
Regulation Name: Medical Absorbent Fiber
Regulatory Class: I
Product Code: FRL
Dated: May 15, 2013
Received: May 17, 2013

Dear Ms. Leander:

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.

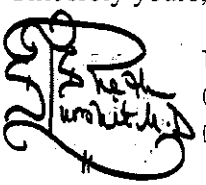
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

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

Enclosure

Indications for Use

510(k) Number (if known): K121898

Device Name: *Stay Fresh* Skin Fold Management Textile (SFMT)

Indications for Use:

The Stay Fresh Skin Fold Management Textile is a skin protectant intended to be used between skin folds and in other skin-to-skin contact areas to provide moisture management and reduce friction. The Stay Fresh Skin Fold Management Textile contains hydrogen peroxide, which reduces bacterial populations in the fabric.

Prescription Use _X_ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
ivision of Anesthesiology, General Hospital
ifection Control, Dental Devices

Date: 2013.05.24 13:20:56 -04'00'

510(k) Number: K121898