K991757

AUG 12

SUMMARY OF SAFETY AND EFFECTIVENESS

February 19, 1999

1. COMPANY INFORMATION:

Furlong Industries
311 N. Slusser Street
Grayslake, IL 60030
Registration #: Pending
Phone: (847) 548-6831
Contact Name: Pete Furlong
Contact Title: President

2.

DEVICE NAME:	Non-Absorbable Gauze for External Use
PROPRIETARY NAME:	None
COMMON NAME:	Gauze Sponges/Bandages
CLASS:	I
PRO CODE:	79FRO Dressing 79EFQ Sponge, Gauze
PERFORMANCE STANDARDS:	None

3. MANUFACTURING SITE INFORMATION:

Furlong Industries
311 N. Slusser Street
Grayslake, IL 60030
Phone: 847-548-6831
Contact Person: Pete Furlong

4. INTENDED/INDICATIONS FOR USE:

These devices are indicated for external use only for cleaning wounds, scrubbing, dressing and fluid absorption.

5. CLINICAL TESTS:

There are no clinical studies that have been performed on these devices, both for the predicate and the new devices.

Furlong Industries
311 N. Slusser Street
ph. (847) 548-6831
Grayslake, IL 60060

Pete Furlong, President

SUMMARY OF SAFETY AND EFFECTIVENESS, continued

6. TECHNOLOGICAL CHARACTERISTICS:
There are no technological characteristics to the new device.

7. DESCRIPTION:
Furlong Industries' Non-X-Ray Detectable Gauze Sponges/Bandages, both sterile and non sterile, consist of cotton, rayon or rayon/polyester formed material and/or cellulose, This device is for external use only for cleaning wounds, scrubbing, dressing and fluid absorption.

8. OTHER INFORMATION:
A reasonable search of all information known or otherwise presently available to Furlong Industries has been conducted, Such a search is defined as examining the Medline Databases, Freedom of Information Services, Inc., competitive literature concerning the safety and effectiveness information for gauze sponges.

Gauze sponges/bandages have been utilized for an extensive period of time for wound scrubbing, cleaning and dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Mr. Pete Furlong
President
Furlong Industries
311 North Slusser Street
Grayslake, Illinois 60060

Re: K991757
Trade Name: Non-Absorbable Gauze for External Use
Regulatory Class: Unclassified
Product Code: EFQ
Dated: May 18, 1999
Received: May 24, 1999

Dear Mr. Furlong:

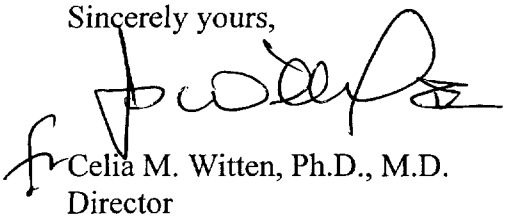
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

Furlong Industries
311 N. Slusser Street
ph. (847) 548-6831
Grayslake, IL 60060

Pete Furlong, President

INTENDED USE

K991757

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510(k) Number (if known): (N/A)

Device Name: Non-Absorbable Gauze for External Use

Indications for Use:

These devices, both sterile and non sterile, are indicated for external use only and are intended to be used to clean wounds, to scrub or prepare incision sites, to absorb fluids, and dress wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991757