

K983450

NOV 12 1998

510(K) SUMMARY

I. ADMINISTRATIVE

Submitter: TC DENTAL PRODUCTS INC.
20957 Currier road (E)
Walnut, CA 91789
Tel:909-839-0868
Fax:909-839-0766

Contact Person: Jen Wang, Vice President

Date of Summary : September 21 1998

II. Device Name

Proprietary Name : STARRYSHINE Gauze Sponges

Classification Name: Gauze Sponges

III. Predicate Device

Surgicide™ Non-Sterile Gauze Sponges 

IV. Device Description:

STARRYSHINE GAUZE SPONGE Are composed of USP type VII gauze, available in the thickness of 8 ply (2" x 2") 4 ply (2" x 2"), it's non-sterile and made with 100% cotton. use in control bleeding, absorb body fluids and protect wounds from contamination.

V. Intended Use

STARRYSHINE Gauze Sponges are used in a dental office or hospital setting where Gauze is required, the instructions for use by physicians using gauze sponges are exactly the same as the instructions for use found on present labeling for similar products currently on the market. It is used to control bleeding, absorb body fluid, and protect wounds from contamination.

VI. Comparison to predicate device

STARRYSHINE GAUZE SPONGES are similar or identical in composition function and intended use to legally marketed gauze sponges, such as Surgicide Non-sterile gauze sponges, all such devices are composed of absorbent gauze in various thickness and size, and had the same intended use.

TC DENTAL PRODUCTS INC. has concluded that the STARRYSHINE Gauze sponges are effective and safe for their intended use and perform as well as legally marketed predicate devices, such as Surgicide Non-sterile gauze sponges.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jen Wang
Vice President
TC Dental Products, Inc.
20957 Currier Road (E)
Walnut, California 91789

Re: K983450
Trade Name: STARRYSHINE™ GAUZE SPONGES
Regulatory Class: Unclassified
Product Code: EFQ
Dated: September 21, 1998
Received: September 30, 1998

Dear Mr. Wang:

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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against

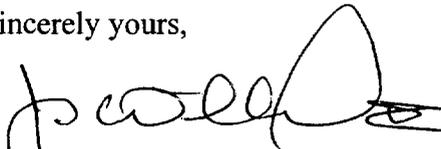
misbranding and adulteration.

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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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) 594-4595. 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,



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

STATEMENT OF INDICATIONS FOR USE

510(K) Number: K983450

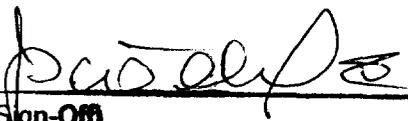
Device Name: STARRYSHINE™ GAUZE SPONGES

Indications for use:

STARRYSHINE Gauze Sponges are intended for use to control bleeding, absorb body fluid, and protect wounds from contamination.

Concurrence of CDRH, Office of the Device Evaluation (ODE)

Prescription Use X OR Over the counter Use _____



(Signature Sign-Off)
Director of General Restorative Devices
510(K) Number K983450