K973145

TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System
510(k) Summary

NOV 19 1997

August, 1997

I. **Company:**

Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System

Classification Name: Bone plate and smooth or threaded metallic bone fixation fastener

III. The TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System consists of a system of small plate and screws of various sizes and shapes. The implant components are fabricated from Ti-6Al-4V titanium alloy as described by ASTM F-136 or its ISO equivalent. Alternatively, the entire system or parts of it may be made out of commercially pure titanium. The TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System may be supplied either sterile or non-sterile.

IV. The TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System is intended for use in any oral-maxilio-craniofacial surgical procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together.

V. The TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System was claimed to be substantially equivalent to commercially available medical devices. Literature concerning these devices was supplied in support of establishing equivalence.

Mechanical test data were provided in support of this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Sofamor Danek USA, Incorporated
1800 Pyramid Place
Memphis, Tennessee 38132

NOV 19 1997

Re: K973145
Trade Name: TIMESH® Titanium Mini-Softplate and Micro-Soft Plate/Screw System
Regulatory Class: II
Product Code: JEY
Dated: August 20, 1997
Received: August 22, 1997

Dear Dr. Treharne:

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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System

Indications For Use:

The TIMESH® Titanium Mini-Softplate/Screw and Micro-Softplate/Screw System is intended for use in any oral-maxilio-cranio-facial surgical procedure, either orthognathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K973245

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

(Optional Format 1-2-96)