

K974649

MAY 1 1998

Tru-Flex Post Systems, Inc.
Bio-Post 510(k) Notification
Attachment 1

**Bio-Post Dental Post System
Summary of Safety and Efficacy**

Submitter Information:

Tru-Flex Post Systems, Inc.
438 Bay Ridge Parkway
Brooklyn, NY 11209

510(k) Summary Prepared by:

Carolann Kotula
Official Correspondent for Tru-Flex Post Systems
c/o mdi Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021

Phone: (516) 482-9001
Fax: (516) 482-0186

Date 510(k) Summary Prepared: December 9, 1997

Name/Classification of the Device:

Classification Name:	Root Canal Post
Common Name:	Root Canal Post
Proprietary Name:	Bio-Post Dental Post System
Classification:	Class I: 21CFR 872.3810

Identification of the Legally Marketed Device to which the Submitter Claims Equivalence: These devices are substantially equivalent to austenitic alloy root canal posts legally marketed by Essential Dental Systems.

Comparative Information: Tensile strength and modulus of elasticity of the Bio-Post was compared to aluminum, titanium, and stainless steel posts. The results show the Bio-Post has a lower modulus, and higher tensile properties than alloy and steel posts.

Description of the Subject Device: The Bio-Post is fabricated from a composite of medical grade continuous glass fibers specifically oriented in a vinyl ester matrix around a surgical grade stainless steel wire. The device is radiopaque, and will be available in standard sizes.

Intended Use of the Subject Device: The device is intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

Technological Characteristics of the Subject Device: The material and material orientation of the Bio-Post is a technological characteristic more advanced than the traditional root canal posts made of austenitic alloys. This allow the Bio-Post to have a lower modulus, and higher tensile properties than alloy and steel posts.

Biocompatibility testing of the materials showed them to be biocompatible.



MAY | 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tru-Flex Post Systems Incorporated
C/O Ms. Carolann Kotula
Vice President RA/QA
mdi Consultants, Incorporated
55 Northern Boulevard
Great Neck, New York 11021

Re: K974649
Trade Name: Bio-Post Dental Post System
Regulatory Class: I
Product Code: ELR
Dated: April 7, 1998
Received: April 8, 1998

Dear Ms. Kotula:

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.

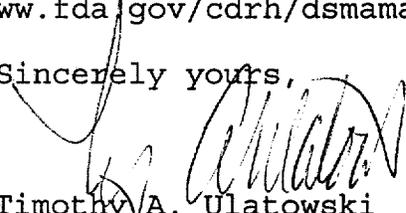
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice 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 pre-market 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) 594-4692. 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): K974649

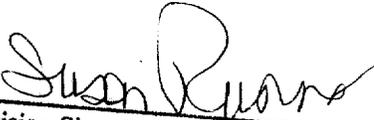
Device Name: Tru-Flex Post Systems Inc., Bio-Post Dental Post System

Indications for Use:

The Bio-Post is a dental root canal post intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

(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 K974649

Prescription Use _____
(per 21 CFR 801.109)

OR

Over the Counter Use _____