



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven R. Buckley
Sabre-K Limited
Golf Road, Hale, Altrincham
Cheshire WA 15 8AH
UNITED KINGDOM

Re: K983161
Trade Name: Kurer Crown Saver K4 Anchor System-The
Universal Kit, Kurer Standard K4 Anchor
Regulatory Class: I
Product Code: ELR
Dated: September 2, 1998
Received: September 9, 1998

Dear Mr. Buckley:

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 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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

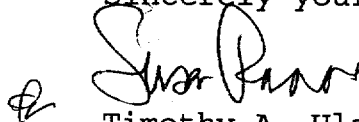
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Page 2 of 2510(k) Number (if known): K 983161Device Name: KURER K4 ANCHOR SYSTEM

Indications For Use:

The K4 products fall into the general category of prefabricated (preformed) posts which comprises threaded and non-threaded versions. The K4 system is designed so that the posts are cemented into canals tapped previously with a thread. This means that the K4 system is pre-threaded and therefore placement is passive (not active) as the posts themselves are not cutting into the dentine at the cementation stage. If placed in accordance with the instructions the process will largely eliminate fitting stress.

Posts are placed to support a core so that a crown can complete a tooth restoration, or to stop the coronal tooth substance from shearing off.

The introduction of titanium versions of certain of the K4 products does not change the method or the purpose of the placement. The dentist is simply to be offered a choice of post material. We will not seek to influence the dentist's decision.

Sub

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

Concurrence of CDRII, Office of Device Evaluation (ODE)Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Susan D. Rums
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Services510(k) Number K983161