K061804

SECTION VI

OCT - 6 2006

510 (K) SUMMARY

Submitter of 510 (k):	etkon international gmbh Lochhamer Schlag 6 81266 Graefelfing Phone: +49–89–89827255 Telefax +49–89–89827247 e-mail info@etkon.de Web: http://www.etkon.de
Contact person	Kirsti Havenstein Regulatory affairs representative Phone: +49–89–89827254 Telefax +49–89–89827250 e-mail kirsti.havenstein@etkon.de
Date of Summary	June 14, 2006
Trade Name	*ZERION*
Classification name:	Porcelain Powder for clinical use
Product code	EIH
C.O.R. section	872.6660
Classification	Class II
Legally marketed equvalent device	XAWEX G 700
510 (k) number	K050903
Device Description	*ZERION* is a dental ceramic being composed of partially sintered yttrium oxide stabilized zirconium oxide. *ZERION* is designed for manufacturing of all–ceramic dental restorations like crown, bridgework, and related dental appliances to be machined on milling centers using CAD/CAM techniques for design and processing. *ZERION* is designed for use as dental restorations like single tooth crowns or bridgeworks with up to two pontics for the anterior and posterior teeth regions equally. The restorations made–up of *ZERION* are destinated for the sole use of particular patients.

ZERION is biocompatible and insoluble in water. Due to the outstanding high strength of densely sintered ceramic Zerion-restorations enable dental technicians to design finely shaped, precise, and filigree framework. The characteristic white color offers an outstanding basis for aesthetical restorations. All these advantages together ensure safe, resistant, and effective dental restorations.

ZERION substructures are well suited to be veneered with suitable dental porcelains using the layering technique.

ZERION meets all applicable requirements for biocompatible dental restorations of the uInternational standard ISO 6872:1999 „Dental ceramic". It meets even the the international standard 13356:1997 „Implants for surgery – Ceramic materials based on Yttria-stabilized tetragonal zirkonia".

The partially sintered *ZERION* blanks are fabricated in two different types distincted by their presintered density and each type available as disks with different dimensions as follows:

type of product	disk diameter [mm]	heigth of disks [mm]					
ZERION alpha	98	10	12	14	18	20	25
ZERION beta	98	10	12	14	18	20	25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Matthias Zitzmann
Managing Director
ETKON International, GmbH
Lochhamer Schlag 6
Grafelfing, Bavaria,
GERMANY 82166

OCT 6 - 2006

Re: K061804
Trade/Device Name: Zerion Alpha, Zerion Beta
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 19, 2006
Received: September 21, 2006

Dear Mr. Zitzmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061804

SECTION IV

INDICATIONS FOR USE

ZERION is a dental ceramic designed for the fabrication of dental restorations by dental technicians.

ZERION delivery state is a yttria (yttrium oxide) – stabilized tetragonal zirconia (zirconium oxide) powder, already partially sintered and made for machining by use of CAD/CAM–techniques. The machined frameworks (dental crown and bridge works) are then sintered to full density.

ZERION is especially designed for use as framework (substructure) for dental restorations including single tooth or bridge type applications on both anterior and posterior locations.