



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KaVo America Corporation
C/O Roger W. Barnes, Ltd.
Regulatory Consultant
342 Sunset Bay Road
Hot Springs, Arkansas 71913

FEB 22 2000

Re: K983658

DIAGNOdent Laser Fluorescence Caries Detection Device
Evaluation of Automatic Class III Designation

Dear Mr. Barnes:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition, submitted in accordance with section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act), for classification of the DIAGNOdent device for aiding in the diagnosis of dental caries. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the DIAGNOdent device, and substantially equivalent devices of this generic type, into class II under the generic name, *Laser Fluorescence Caries Detection Device*.

FDA identifies this generic type of device as a dental device under 21 CFR 872.1745. This generic type of device consists of a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.

In accordance with section 513(f)(1) of the act, devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify

the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the *Federal Register* classifying the device.

In accordance with section 513(f)(1) of the act, FDA issued an order on June 10, 1999, automatically classifying the DIAGNOdent device in class III, because it was not within a type of device which had been introduced into interstate commerce before enactment of the amendments, nor subsequently reclassified into class I or class II. Furthermore, in response to a petition submitted in accordance with section 513(f)(2), FDA determined that the DIAGNOdent device was not a candidate for classification under this section of the act. As a result of an appeal filed under 21 CFR Part 10.75, FDA reopened the previously submitted petition requesting classification of the DIAGNOdent device into class II on December 23, 1999. In order to classify the DIAGNOdent device into class I or class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After a reevaluation of the information submitted in the petition, its amendments, and the original 510(k) (K983658), FDA has determined that the DIAGNOdent device, intended to aid in the diagnosis of dental caries, can be classified in class II with the establishment of special controls. FDA believes that special controls, when combined with general controls, provide reasonable assurance of the safety and effectiveness of the device. Please note: this response to your 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.

FDA has identified one risk to health associated with this type of device. This risk involves the possible error in diagnosis of dental caries when the DIAGNOdent is either misused, or its results are not properly corroborated using other standard diagnostic techniques. Therefore, the DIAGNOdent is subject to the following special controls which when combined with the general controls of the act, provide reasonable assurance of the safety and effectiveness of the device:

1. restrictions on the sale, distribution, and use of the device to prescription use in accordance with 21 CFR 801.109;
2. clinical studies, or other relevant information, that demonstrates that the device aids in the detection of tooth decay by measuring increased laser induced fluorescence; and
3. labeling that includes detailed use instructions with precautions that urge users to (i) read and understand all directions before using the device, (ii) store probe tips under proper conditions, (iii) properly sterilize the emitter-detector handpiece before each use, and (iv) properly maintain and handle the instrument in the specified manner and condition.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device, and therefore, the device type is not exempt from the premarket notification requirements. Thus, persons who intend to market a device of this type must submit a premarket notification to FDA and receive agency clearance prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order. If you have any questions concerning this classification order, please contact Robert S. Betz, DDS, at 301-827-5283.

Sincerely,



Philip J. Phillips
Deputy Director for Science
and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health