DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Diamond General Development Corporation
C/O John F. Schaefer, Ph.D.
JFS Associates Incorproated
44 Manor Drive
Ramsey, New Jersey 07446

Re: K980749
Evaluation of Automatic Class III Designation - Diamond Probe®/Perio 2000 System - K980749
Dated: May 18, 1998
Received: May 18, 1998

Dear Dr. Schaefer:

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 Food, Drug, and Cosmetic Act, for classification of the Diamond Probe®/Perio2000 System, that is intended to measure periodontal pocket probing depths, evaluate the presence or absence of bleeding on probing, and to detect the presence of sulfides in periodontal pockets of adult patients. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Diamond Probe®/Perio2000 System, and substantially equivalent devices of this generic type into class II under the generic name, sulfide detection device.

FDA identifies this generic type of device as a dental device under 21CFR 872.1870, as an in vivo sulfide detection device, consisting of an AC-powered control unit, probe handle, probe tips, cables and accessories. This device is intended to manually measure periodontal pocket probing depths and evaluate the presence or absence of bleeding on probing. In addition, it is intended to detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of adult patients with periodontal diseases.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (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 the 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, with in 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 May 15, 1998, automatically classifying the Diamond Probe®/Perio2000 System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. On May 18, 1998, FDA filed your petition requesting classification of the Diamond Probe®/Perio2000 System into class II. The petition was submitted under section 513(f)(2) of the act. In order to classify the Diamond Probe®/Perio2000 System into 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 review of the information submitted in the petition, its amendments, and K980749, FDA has determined that the Diamond Probe®/Perio2000 System intended to measure periodontal pocket probing depths, evaluate the presence or absence of bleeding on probing, and to detect the presence of sulfides in periodontal pockets can be classified in class II with the establishment of special controls. FDA believes that class II with special controls provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated with this type of device: (1) risk of electrical shock to user or patient, (2) electromagnetic disturbances in electronic medical equipment in the immediate vicinity of the device when

in use, (3) possible errors in diagnosis of adult periodontal diseases when used alone. When used alone, this device may indicate that treatment may be needed when not actually required. It may also fail to indicate that an active gingival infection is present.

In addition to the general controls of the Act, the Diamond General Probe®/Perio 2000 System is subject to the following special controls in order to provide reasonable assurance of the safety and effectiveness: (1) The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. (2) Manufacture of this device is in accordance with recognized voluntary standards of biocompatibility, recognized electrical and electromagnetic standards, and sterilization and sterilization validation standards. (3) Clinical trials demonstrating that the device measures probing depths, evaluates the presence or absence of bleeding on probing, as well as detecting the presence of sulfides in periodontal pockets in the evaluation of periodontal diseases in adult patients. (4) The labeling must include precautions indicating the need (i) to read and understand all directions before using this device, (ii) store probe tips and solutions under proper conditions, (iii) to properly sterilize the probe handle, (iv) to maintain and handle the instrument in a proper manner and condition, and (v) to discard the probe tip after each clinical appointment, when pre-use sterility of the probe tip is considered to be compromised, or after using the system checking substance.

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 the device, and therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification 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.

FDA also requests that you submit final labeling to us as soon as possible, and before commercial distribution of your device. If you have any questions concerning this classification order, please contact Robert S. Betz, DDS at 301-827-5283.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Devices Evaluation
Center for Devices and
Radiological Health