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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 98P-0731]

Dental Devices; Classification of Sulfide Detection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the sulfide detection device into class II (special controls). The special controls that will apply to the sulfide detection device are restriction to prescription use, conformance with recognized standards relating to biocompatibility, electrical safety and sterility, submission of performance data from analytical and clinical studies demonstrating device effectiveness and adherence to specific labeling requirements. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Modernization Act of 1997. The agency is classifying sulfide detection devices into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

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EFFECTIVE DATE: (Insert date 30 days after date of publication in the FEDERAL REGISTER.)

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of the enactment of the Medical Device Amendments 1976, generally referred to as postamendments devices are classified automatically by statute into class III without any 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, 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 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such as request, classify the device by written order. 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 announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on May 15, 1998, classifying sulfide detection devices in class III. On May 18, 1998, Diamond General Development Corp. submitted a petition requesting classification into class II of the Diamond Probe®/Perio 2000 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. After reviewing the information submitted in the petition, its amendments, K980749, and medical literature, FDA concludes that this device, and substantially equivalent devices of this generic type, can be classified into class II with the establishment of special controls. In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to develop special controls to provide such assurance. After reviewing the information submitted in the petition, FDA determined that sulfide detection devices can be classified into class II with the establishment of special controls. FDA believes that general controls and special controls will provide reasonable assurance of safety and effectiveness of the device.

FDA has identified the following risks to health associated with this type of device: (1) Risks associated with the inability to develop adequate directions for use; (2) risks associated with biocompatibility, electrical

safety, and sterility; (3) risks related to inaccurate device performance; and (4) risks associated with improper device use.

FDA determined that the special controls described below address these risks and provide reasonable assurance of the safety and effectiveness of the device. Therefore on July 17, 1998, FDA issued an order to the petitioner classifying the sulfide detection device as described previously into class II subject to the special controls described below.

Additionally, FDA is codifying the classification of this device by adding § 872.1870 Sulfide detection device.

In addition to the general controls of the act, the sulfide detection device is subject to the following special controls which, combined with general controls, provide reasonable assurance of the safety and effectiveness of the device: (1) Restriction of the sale, distribution, and use of this device to prescription use in accordance with 21 CFR 801.109; (2) conformance with recognized standards for biocompatibility, electrical safety, and sterility; (3) clinical and analytical testing sufficient to demonstrate that the device accurately measures probing depths, detects the presence or absence of bleeding on probing, and accurately detects the presence of sulfides in periodontal

pockets in adult patients; (4) labeling that includes proper instructions for device storage, use, and maintenance.

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 efficacy 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.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small

Business Regulatory Flexibility Act (Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order, and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices in class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not

impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Act is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, under the Paperwork Reduction Act of 1995 is not required.

V. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Diamond General Development Corp., dated May 18, 1998.

2. Solis-Gaffar, M. C., T. Fischer, and A. Gaffar, "Instrumental Evaluation of Odor Produced by Specific Oral Microorganisms," Journal of Cosmetic Chemistry, vol. 30, pp. 241 to 247, 1979.

3. Solis-Gaffar, M. C., K. N. Rustogi, and A. Gaffar, "Hydrogen Sulfide Production from Gingival Crevicular Fluid," Journal of Periodontology, vol. 5 (10), pp. 603 to 606, 1980.

List of Subjects in 21 CFR Part 872
Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872--DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.1870 is added to subpart B to read as follows:

§ 872.1870 Sulfide detection device.

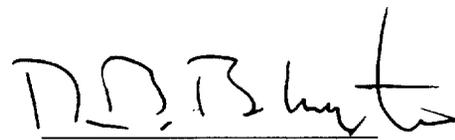
(a) Identification. A sulfide detection device is a device consisting of an AC-powered control unit, probe

handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.

(b) Classification. Class II (special controls)
prescription use in accordance with § 801.109 of this

chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

Dated: 8-25-98
August 25, 1998



D.B. Burlington
Director
Center for Devices and Radiological Health

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