DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FMG Innovations, Inc.
c/o Linda D. Bentley
Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, PC
One Financial Center
Boston, MA 02111

MAR 27 2006

Re: K051653
Trade/Device Name: The HealthCheck™ Home Test for Loss of Sense of Smell
Regulation Number: 21 CFR 874.1600
Classification: Class II
Product Code: NRK

Dear Ms. Bentley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the HealthCheck™ Home Test for Loss of Sense of Smell that is intended for over-the-counter use, in accordance with 21 CFR 801 Subpart C, to allow an individual to determine if a loss of olfactory function (the ability to smell) is present or has occurred. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the HealthCheck™ Home Test for Loss of Sense of Smell, and substantially equivalent devices of this generic type into class II under the generic name, Olfactory Test Device. This order also identifies special controls applicable to this device.

FDA identifies this generic type of device as:

> An olfactory test device is used to determine whether an olfactory loss is present. The device includes one or more odorants that are presented to the patient's nose to subjectively assess the patient's ability to perceive odors.

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 type.

On July 29, 2004, FDA filed your petition requesting classification of the HealthCheck™ Home Test for Loss of Sense of Smell into class I. The petition was submitted under section 513(f)(2) of the act. Previously, on May 27, 2004, in accordance with section 513(f)(1) of the act, FDA had issued an order automatically classifying the HealthCheck™ Home Test for Loss of Sense of Smell into 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.

In order to classify the HealthCheck™ Home Test for Loss of Sense of Smell into class I or 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 classification petition, FDA has determined that The HealthCheck™ Home Test for Loss of Sense of Smell can be classified in class II with the establishment of special controls.

The potential risks identified by FDA for the HealthCheck™ Home Test for Loss of Sense of Smell are 1) failure of the device to reliably detect a loss of olfactory function, and 2) user error. FDA believes that the manufacturer can provide a reasonable assurance of safety and effectiveness for this device through specials controls for performance testing and labeling of the device.

Therefore, in addition to the general controls of the act, the HealthCheck™ Home Test for Loss of Sense of Smell is subject to a special controls guidance document with recommendations on performance testing and labeling. 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 not necessary to provide reasonable assurance of the safety and effectiveness of the device when the device is intended to determine whether an olfactory loss is present. Devices intended for use in screening or diagnosis of diseases or other conditions (other than loss of olfactory function) will be subject to premarket review. Thus, persons who intend to market this device to determine whether a loss of olfactory function is present need not submit to FDA a premarket notification submission containing information on the olfactory test device they intend to market prior to marketing their device subject to the limitations on exemptions in 21 CFR 874.9.

A notice announcing this classification order will be published in the **Federal Register**. A copy of the petition and the order will be on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 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 Eric A. Mann, M.D., Ph.D. at (301) 594-2080.

Sincerely,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health