DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Joan Gordon
President
Maine Molecular Quality Controls, Inc.
10 Southgate Road, Suite 170
Scarborough, ME 04074

OCT 12 2006

Re: k060070
Evaluation of Automatic Class III Designation
INTROL™ CF Panel I Control
Regulation Number: 21 CFR 866.5910
Classification: Class II
Product Code: NZB

Dear Ms. Gordon:

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 INTROL™ CF Panel I Control that is intended for *in vitro* diagnostic use as a quality control to monitor analytical performance of the extraction, amplification and detection steps of diagnostic assays used in the detection of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations and variants. This product is intended to be extracted and analyzed routinely with each CFTR assay run.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the INTROL™ CF Panel I Control into class II under the generic name, Quality Control Material for Cystic Fibrosis Nucleic Acid Assays. This order also identifies the special controls applicable to this device, and substantially equivalent devices of this generic type.

FDA identifies this generic type of device as:

21 CFR 866.5910 Quality Control Material for Cystic Fibrosis Nucleic Acid Assays. A quality control material for cystic fibrosis nucleic acid assays is a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic and cell line based DNA controls.

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, 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 type. 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 August 14, 2006, FDA filed your petition requesting classification of the INTROL™ CF Panel I Control into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on August 7, 2006, affirming that the INTROL™ CF Panel I Control was classified in class III, because it was not substantially equivalent to a class I or class II device.

In order to classify the INTROL™ CF Panel I Control 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 information submitted in the petition, FDA has determined that the INTROL™ CF Panel I Control, intended for *in vitro* diagnostic use as a quality control to monitor analytical performance of the extraction, amplification and detection steps of diagnostic assays used in the detection of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene mutations and variants, can be classified in class II with the establishment of special controls.

QC material is intended to help monitor reliability of a test system. Therefore, failure of the QC material for cystic fibrosis nucleic acid assays to perform as indicated may lead to error in assessment of test results, and reporting of inaccurate results. This could potentially lead to patient mismanagement. For example, if the controls fail even though the test system was accurate, this may lead to unnecessary retesting, and delay in reporting results. In cases of patient samples that are difficult to obtain, this may cause additional increased risk to the patient. Conversely, if a QC material does not accurately reflect when the test system has failed, this may lead to false assurance of test operability, and reporting of inaccurate patient results. The inability to accurately reflect test system failure with patient samples may be due to the control not accounting for all system or sample variances. In some cases controls may only be intended to account for some system or sample variances, rather than for all such variances. The measures FDA recommends to mitigate these risks are described in the guidance document, "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays," which includes recommendations for performance validation and labeling.

assays is subject to the following special controls: "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays." 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 submission containing information on the Quality Control Material for Cystic Fibrosis Nucleic Acid Assays they intend to market 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, 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 Zivana Tezak at (240) 276-0495 ext. 117.

Sincerely yours,

for Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health