K083171

MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.

10 Southgate Road, Suite 170
Scarborough, Maine 04074
Phone: 207-885-1072; Fax: 207-885-1079
www.mmqci.com

APPENDIX 4

510 (k) Summary

DEC 16 2008

Applicant Contact Information:

Applicant:	Maine Molecular Quality Controls, Inc. (MMQCI)
Address:	10 Southgate Road, Suite 170 Scarborough, Maine 04074
Contact Person:	Joan H. Gordon, President
Phone Number:	207-885-1072
Fax Number:	207-885-1079
Preparation Date:	October 19, 2008

Device Trade Name:

INTROL™ CF Panel I Control

Device Regulatory Information:

Regulation No.:	21 CFR 866.5910
Common name:	Quality control, genetic, DNA control
Classification Name:	Quality Control Material for Cystic Fibrosis Nucleic Acid Assays
Regulatory Class:	Class II
Product Code:	NZB
Panel:	Immunology (82)

Predicate Device:

K060070 INTROL™ CF Panel I Control

Device Description (same as predicate):

Modified INTROL™ CF Panel I Control consists of synthetic (recombinant) CFTR DNA suspended in a matrix of carrier DNA of non-human species, preservatives, dye, and stabilizers. CFTR DNA is stabilized in the matrix and released when processed through common extraction methods as if it were a whole blood specimen. INTROL™ CF Panel I Control was modified to contain additional wild type CFTR DNA required for primer annealing of some CFTR detection assays.

MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.

10 Southgate Road, Suite 170
Scarborough, Maine 04074
Phone: 207-885-1072; Fax: 207-885-1079
www.mmqci.com

510(k) Summary (Cont.)

Device Intended Use (same as predicate):

INTROL™ CF Panel I Control 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 FibrosisTransmembrane Conductance Regulator (CFTR) gene mutations and variants. This product is intended to be extracted and analyzed routinely with each CFTR assay run. The INTROL™ CF Panel I Control is designed to monitor the detection of 38 CFTR mutations associated with cystic fibrosis, including the 23 mutations recommended for testing by American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG). The INTROL™ CF Panel I Control also monitors 3 polymorphisms (I506V, I507V, F508C) and the 5/7/9T variants.

Substantial Equivalence:

In view of technical, physical, and performance characteristics, MMQCI believes modified INTROL™ CF Panel I Control is substantially equivalent to INTROL™ CF Panel I Control (K060070) as to intended use and fundamental scientific technology.

Summary of Performance Nonclinical Data

Verification and validation testing performed as needed according to risk analysis showed that modified INTROL™ CF Panel I Control performed as well or better than INTROL™ CF Panel I Control (K060070). Test methods were the same as those used for 510(k) submission of the predicate. Design outputs of modified INTROL CF Panel I Control meet design inputs in conformance with design control requirements as specified in 21 CFR 820.30.

Conclusions

Based on analysis and performance testing, we conclude that modified INTROL™ CF Panel I Control is substantially equivalent to INTROL™ CF Panel I Control (K060070), is as safe and effective as the predicate, and performs better than the predicate in certain CFTR detection assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Maine Molecular Quality Controls, Inc.
c/o Ms. Joan H. Gordon
President
10 Southgate Road, Suite 170
Scarborough, Maine 04074

DEC 1 6 2008

Re: k083171
Trade/Device Name: INTROL™ CF Panel I Control
Regulation Number: 21 CFR 866.5910
Regulation Name: DNA quality control material for genetic testing
Regulatory Class: Class II
Product Code: NZB
Dated: October 19, 2008
Received: October 27, 2008

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

MMQCI

APPENDIX 2

Indications for Use Statement

510 (k) Number: K083171

Device Name: INTROL™ CF Panel I Control

Indications for Use:

The intended use for the cleared and modified INTROL™ CF Panel I Controls is the same. The INTROL™ CF Panel I Control 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.

The INTROL™ CF Panel I Control is designed to monitor the detection of 38 CFTR mutations associated with cystic fibrosis, including the 23 mutations recommended for testing by American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG). The INTROL CF Panel I Control also monitors 3 polymorphisms (I506V, I507V, F508C) and the 5/7/9T variants.

For *in vitro* diagnostic use.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K083171