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Facsimile transmittal

To: Donald MOSSMAN Fax: 508--418-1397

From: RENITA HOARD Date: 11/18/08

Re: Pages: 3

CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service
Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

November 4, 2008

Mossman Associates, Inc.
c/o Donald Mossman , President
9 Village Cirlcle
Milford, MA 01757 US

Document No: k963733/A012
Re: k963733
Received: September 30, 2008

Waiver Granted Notification

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your application for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. We are pleased to inform you that your test system(s) as identified below is waived:

Test System/Analyte (s) : (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved or cleared by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above. This complexity categorization is effective as of the date of this notification.

This categorization will be reported on FDA's home page http://www.fda.gov/cdrh/clia and categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you have any questions regarding this complexity categorization, please contact Courtney Harper at 240-276-0694.

Sincerely yours,

Steven Gutman

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

ATTACHMENT

Document Number : k963733

Test System : Mossman Associates, Inc. NicCheck I Test Strips
Analyte : Nicotine And/Or Metabolites
Complexity : WAIVED