



10903 New Hampshire Avenue
Silver Spring, MD 20993

MEDICA CORP.
c/o Photios Makris
5 Oak Park Drive
Bedford, MA 01730

DEC - 6 2011

Re: k111363
Trade Name: PPX REAGENT,
PPX CALIBRATORS,
PPX QC MATERIAL
Regulation Number: 21 CFR §862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Codes: JXN, DLJ, LAS
Dated: November 01, 2011
Received: November 29, 2011

Dear Photios Makris:

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.

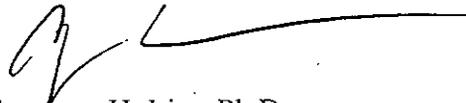
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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 (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111363

Device Name: EasyRA Propoxyphene (PPX) Reagent

Indications For Use: The EasyRA PPX reagent is intended for the qualitative and semi-quantitative measurement of Propoxyphene (PPX) in human urine, using MEDICA's EasyRA Chemistry Analyzer in clinical laboratories. The cut-off point of the assay is 300ng/ml, and provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory method. The semi-quantitative mode is intended to enable laboratories to determine the appropriate dilution of the specimen for confirmation by a reference method such as GC/MS or LC/MS and to allow laboratories to establish effective quality control procedures for the PPX assay.

Device Name: EasyRA Propoxyphene (PPX) Calibrators

Indications For Use: Medica's Propoxyphene (PPX) Calibrators are intended for the calibration of the PPX Enzymatic Immunoassay to estimate propoxyphene in human urine, using Medica's PPX reagent on the EasyRA clinical chemistry analyzer.

Device Name: EasyRA Propoxyphene (PPX) QC Material

Indications For Use: Medica's Propoxyphene (PPX) QC Materials are intended for the validation of the PPX Enzymatic Immunoassay to estimate propoxyphene in human urine, using Medica's PPX reagent and PPX calibrator on the EasyRA clinical chemistry analyzer.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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