JUN 1 0 2002

Starplex Scientific Inc.
510k Submission
K021006
Additional Information
6/6/02

510 (K) SUMMARY

Date of Summary

June 4, 2002

Product Name:

STARTOX™

Sponsor and Manufacturer:

Starplex Scientific, Inc.
50 Steinway Blvd.
Etobicoke, Ontario, Canada M9W 6Y3

Correspondent:

Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device:

Product: Rapid Drug Screen – 9 panel
Manufactured by: American BioMedica Corp
510k Number: K002447

Product Description:

A lateral flow immunoassay for the detection of drugs of abuse.

INTENDED USE:

STARTOX™ Drugs of Abuse Screening Test is a one-step lateral flow immunoassay intended for the simultaneous detection of multiple drug analytes in urine. STARTOX™ is intended for use in the qualitative detection of drugs of abuse at the following Substance Abuse Mental Health Services Administration (SAMHSA) recommended levels:

Compound	Abbreviation	Level
Amphetamine (d-amphetamine sulfate)	AMP	1000 ng/ml
Opiates (morphine-3-P-D glucuronide)	OPIATES	2000 ng/ml
Phencyclidine (phencyclidine HCl)	PCP	25 ng/ml
Cocaine (benzoylecgonine)	COCAINE	300 ng/ml
Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid)	THC	50 ng/ml

STARTOX™ Drugs of Abuse Screening Test provide only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

PERFORMANCE CHARACTERISTICS:

STARTOX™ drugs of abuse screening test detects 5 drugs in human urine at the levels indicated.

STARTOX™ is substantial equivalent to Rapid Drug Screen 9 panel manufactured by American BioMedica Corporation 510k number K002447.

Product performance was compared Medtox Profile II manufactured by Medtox Diagnostics. Ninety (90) samples were tested against each drug, 50 negative which were confirmed to be drug free and 40 positive specimens for each drug were screened as positive by Emit, confirmed and quantified by GC/MS.

The STARTOX™ Drugs of Abuse Screening Test was compared to a FDA substantially equivalent approved device, Medtox Profile II. STARTOX™ demonstrated greater than 99% accuracy with when compared to a legally marketed device.

Reproducibility was evaluated using control urines containing drug concentrations above and below the stated cut-off. Negative controls were also tested. The results confirmed the reproducibility of the STARTOX™ Drugs of Abuse Screening Test.

CONCLUSION:

STARTOX™ Drug of Abuse Screening Test is substantially equivalent to ABMC Rapid Drug Screen multi-drug products (K012159, K002447) previously cleared for market as demonstrated by the results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 0 2002

Starplex Scientific, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k021006
Trade/Device Name: Startox™ Drug of Abuse Screening Test
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ; DJG; LCM; DIO; LDJ
Dated: March 27, 2002
Received: March 28, 2002

Dear Ms. White:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:
Device Name: STARTOX™ Drug of Abuse Screening Test

Indication for Use:
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For professional use only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021006

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**