SEP 2 1 2009

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K092051

COMPANY/CONTACT PERSON

Lisa Charter
Manager, Regulatory Affairs
Microgenics Corporation
Thermo Fisher Scientific
Specialty Diagnostics Division, CDx Fremont
46360 Fremont Blvd.
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DATE PREPARED

July 16, 2009

DEVICE NAME

Trade Names:
Thermo Scientific MAS® chemTRAK® H Liquid Assayed Chemistry Controls
Thermo Scientific Moni-Trol® H Liquid Assayed Chemistry Controls

Common Names:
chemTRAK® H Liquid Assayed Chemistry Controls
Moni-Trol® H Liquid Assayed Chemistry Controls

Device Classification: Class I

Classification Panel: Quality Control Material (Assayed and Unassayed) for Clinical Chemistry

Regulation number: 21 CFR 862.1660

Product Code: JJY

INTENDED USE:

chemTRAK® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations

with expected ranges as a means of assuring consistent performance of reagent and instrument.

Moni-Trol® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

SUBSTANTIALLY EQUIVILANT PREDICATE DEVICE

Thermo Scientific MAS® chemTRAK® H and Thermo Scientific Moni-Trol® H are substantially equivalent to the previously cleared MAS® chemTRAK® H, DADE® Moni-Trol® H and OLYMPUS Chemistry Control (K030942)

DESCRIPTION OF DEVICE

This product is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various animal extracts and other non-protein materials including drugs, drug metabolites and purified chemicals. Amylase, ALT/GPT, AST/GOT, CK and lipase are obtained from porcine tissue; alkaline phosphatase and GGT are from bovine tissue; LDH is from avian tissue. Preservatives and stabilizers are added to maintain product integrity.

Comparison of Technological Characteristics

Comparison	Predicate Device, K030942	Modified Device, K092051
Intended Use	chemTRAK® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument. Moni-Trol® H is intended for use as a consistent test sample of known concentration for	chemTRAK® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument. Moni-Trol® H is intended for use as a consistent test sample of known concentration for

	monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
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Matrix	This product is a liquid stable control material prepared from human serum.	This product is a liquid stable control material prepared from human serum.
Storage Condition	-20°C	-20°C

Analyte List	**Predicate Device K030942**	**Modified Device Proposed Analytes (Modifications in bold)**
	Acetaminophen	Acetaminophen
	Acid Phosphatase*	Acid Phosphatase*
	Albumin	Albumin
	Alkaline Phosphatase, ALP	Alkaline Phosphatase, ALP
	Alanine Aminotransferase, ALT	Alanine Aminotransferase, ALT
	Alpha-Fetoprotein, AFP*	Alpha-Fetoprotein, AFP*
	Amikacin	Amikacin

Analyte List, Cont.	Amylase	Amylase
	Apolipoprotein A (APO A)*	**Apolipoprotein A (APO A)♦**
	Apolipoprotein B (APO B)*	**Apolipoprotein B (APO B)♦**
	Aspartate Aminotransferase, AST	Aspartate Aminotransferase, AST
	Bilirubin, Direct	Bilirubin, Direct
	Bilirubin, Total	Bilirubin, Total
	Blood Urea Nitrogen, BUN	Blood Urea Nitrogen, BUN
	Caffeine	Caffeine
	Calcium	Calcium
	Carbamazepine	Carbamazepine
	Carbon Dioxide, CO_2	CO_2
	C3 Compliment	C3 Complement*
	C4 Compliment	C4 Complement*
	C-Reactive Protein, CRP	C-Reactive Protein, CRP*
	Chloride	Chloride
	Cholesterol	Cholesterol
	Creatine Kinase, CK	Creatine Kinase, CK
	Creatinine	Creatinine
	Cyclosporine*	-
	Digoxin	Digoxin
	Disopyramide	Disopyramide
	Ethanol	Ethanol
	Ethosuximide	Ethosuximide
	Ferritin	Ferritin*
	Thiiodothyronine Free T3	Thiiodothyronine Free T3*
	Thyroxine Free T4	Thyroxine Free T4*
	Gamma Glutamyltransferase, GGT	Gamma Glutamyltransferase, GGT
	Gentamicin	Gentamicin
	Glutamate Dehydrogenase, GLDH*	Glutamate Dehydrogenase, GLDH*
	Glucose	Glucose
	Haptoglobin*	Haptoglobin*
	Hydroxybutyrate Dehydrogenase, HBDH*	Hydroxybutyrate Dehydrogenase, HBDH*
	High Density Lipoprotein Cholesterol, HDL	High Density Lipoprotein Cholesterol, HDL
	Human Chorionic Gonadotrophin, hCG	Human Chorionic Gonadotrophin, hCG*
	Immunoglobulin A, IgA	Immunoglobulin A, IgA*
	Immunoglobulin G, IgG	Immunoglobulin G, IgG*
	Immunoglobulin M, IgM	Immunoglobulin M, IgM*
	Iron	Iron
	Lactate Dehydrogenase, LDH	LDH
	Lactic Acid	Lactic Acid
	Lidocaine	Lidocaine

Analyte List, Cont.	Lipase	Lipase
	-	**Lipoprotein (LpA)♦**
	Lithium	Lithium
	Low Density Lipoprotein Cholesterol, LDL	LDL-Cholesterol
	Magnesium	Magnesium
	Methotrexate	Methotrexate
	N-Acetylprocainamide, NAPA	N-Acetylprocainamide, NAPA
	Osmolality	Osmolality
	Phenobarbital	Phenobarbital
	Phenytoin	Phenytoin
	Phosphorus	Phosphorus
	Potassium	Potassium
	Prealbumin	Prealbumin
	Primidone	Primidone
	Procainamide	Procainamide
	Prostate Specific Antigen, PSA	-
	Pseudocholinesterase, PCHE	Pseudocholinesterase
	Quinidine	Quinidine
	Salicylate	Salicylate
	Sodium	Sodium
	Theophylline	Theophylline
	Thyroid Stimulating Hormone, TSH	Thyroid Stimulating Hormone, TSH
	Thyroxine, Total T4	Thyroxine, Total T4
	Tobramycin	Tobramycin
	Total Iron Binding Capacity, TIBC	Iron Binding Capacity, Total
	Total Protein	Total Protein
	Transferrin	Transferrin*
	Tricyclic Antidepressants	Tricyclic Antidepressants
	Triglycerides	Triglycerides
	Thiiodothyronine, Total T3	Thiiodothyronine, Total T3*
	T-Uptake	T-Uptake
	Uric Acid	Uric Acid
	Valproic Acid	Valproic Acid
	Vancomycin	Vancomycin
	Unsaturated Iron Binding Capacity (UIBC)	Unsaturated Iron Binding Capacity (UIBC)*

* Analytes are added, however no claims are made

♦ Analytes are not added, as found in the source material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MicroGenics Corporation,
Thermo Fisher Scientific
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538

SEP 21 2009

Re: k092051
Trade Name: Thermo Scientific MAS® chemTRAK® H Liquid Assayed Chemistry Controls, Thermo Scientific Moni-Trol® H Liquid Assayed Chemistry Controls
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: July 1, 2009
Received: July 7, 2009

Dear Ms. Charter:

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 C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: K092051

Device Name:

Thermo Scientific MAS® chemTRAK® H Liquid Assayed Chemistry Controls
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Indication For Use:

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Moni-Trol® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Prescription Use ✓ And/Or Over the Counter Use

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

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

510(k) K092051