

JUL 12 1999

M E T R I K A

Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94086
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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 991917.

807.92(a)(1) Submitters Information

Contact Person: Nancy Mallinak or Stephen J. Hardt
Address: Ostex International, Inc. Metrika, Inc.
2203 Airport Way South, 510 Oakmead Parkway
Suite 400 Sunnyvale, CA 94086
Seattle, WA 98134
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Date Summary Prepared: June 4, 1999

807.92 (a)(2) Device Information

Trade Name: Osteomark[®] NTx Point of Care (POC) Control Set
Common Name: Assayed Urine Controls
Classification Name: Quality Control Material (Assayed and Unassayed)
(Regulation number) 21 CFR 862.1660

807.92 (a)(3) Predicate Device Information

Name: UrichemTRAK Liquid Assayed Control
Manufacturer: Medical Analysis System, Inc.

807.92 (a)(4) Device Description

The Osteomark[®] NTx Point of Care Control Set is a human urine-based, liquid, 2-level control set to be used in quality control procedures with the Osteomark[®] NTx Point of Care test. The assayed control set is used for evaluating precision and systematic analytical deviations that may arise from reagent or device variations.

807.92 (a)(5) Statement of Intended Use

The Osteomark NTx Point of Care (POC) Controls are assayed for the verification of device performance when using the Osteomark NTx POC for the quantitative measure of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine). The controls are used as consistent test samples of known nM BCE/mM creatinine concentration that may be measured over time as a means of evaluating analytical precision, as well as device performance.

807.92 (a)(6) Summary of Technological Characteristics

**Similarities Between Osteomark® NTx Point of Care Control Set
and UrichemTRAK Liquid Assayed Control**

CHARACTERISTIC	Osteomark® NTx Point of Care Control Set	UrichemTRAK Liquid Assayed Control K981933
Intended Use	The Osteomark NTx Point of Care (POC) Controls are assayed for the verification of device performance when using the Osteomark NTx POC for the quantitative measure of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine). The controls are used as consistent test samples of known nM BCE/mM creatinine concentration that may be measured over time as a means of evaluating analytical precision, as well as device performance.	UrichemTRAK Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many urine determinations. Include UrichemTRAK Control with patient urine specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Matrix	Human urine-based materials, preservative, and food coloring	Human urine-based material and preservative
Testing Environment	professional use	professional use

807.92 (a)(6) Summary of Technological Characteristics (continued)

**Differences Between Osteomark® NTx Point of Care Control Set
and UrichemTRAK Liquid Assayed Control**

CHARACTERISTIC	Osteomark® NTx Point of Care Control Set	UrichemTRAK Liquid Assayed Control K981933
Analyte(s)	cross-linked N-telopeptides of type I collagen and creatinine	(Various urinary constituents) Amylase Urea Nitrogen Calcium Creatinine Glucose Chloride Magnesium Potassium Total protein Sodium Uric acid Microalbumin Phosphorus
Test Method	quantitative	quantitative and qualitative

The differences in the two assayed control materials do not raise new issues of safety and effectiveness.

807.92 (b)(1) to b(3) Performance Data and Conclusion

Three manufactured lots of the Osteomark® NTx POC Control Set were evaluated to assess day to day performance with a single lot of Osteomark® NTx POC device. Each control level per control lot was tested six times a day for five days. The data demonstrated that Osteomark® NTx POC Control Set will evaluate the quality of day to day performance of the Osteomark® NTx POC device. Therefore, Osteomark® NTx POC Control is substantially equivalent to existing products in commercial distribution such as the UrichemTRAK Liquid Assayed Control system.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 12 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Stephen J. Hardt
Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, California 94086

Re: K991917
Trade Name: Osteomark® NTx Point of Care (POC) Control Set
Regulatory Class: I
Product Code: JJW
Dated: June 4, 1999
Received: June 7, 1999

Dear Mr. Hardt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

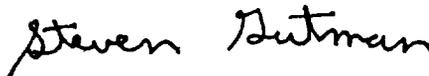
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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: K 991917

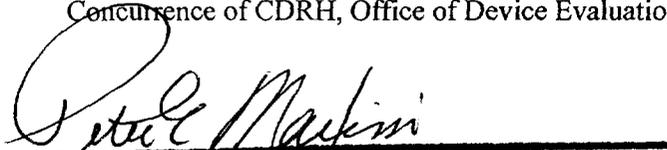
Device Name: Osteomark® NTx Point of Care Control Set

INDICATIONS FOR USE

The Osteomark NTx Point of Care (POC) Controls are assayed for the verification of device performance when using the Osteomark NTx POC for the quantitative measure of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine). The controls are used as consistent test samples of known nM BCE/mM creatinine concentration that may be measured over time as a means of evaluating analytical precision, as well as device performance.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices K991917
510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)