JUL 3 0 2001

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: K011052.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Ostex International, Inc.
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Contact: Ms. Nancy J.S. Mallinak
Vice President, Regulatory and Clinical Affairs
Ostex, International, Inc.

Summary Date: April 4, 2001

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): Osteomark® NTx Point-of Care (POC) for Rx Home-Use

Name (usual): urinary assay for the quantitative ratio of cross-linked N-telopeptides of type I collagen (NTx) divided by creatinine (nM Bone Collagen Equivalents {BCE}/mM creatinine)

Classification(s): ratio numerator: 21 CFR 862.1400, Hydroxyproline Test System
ratio denominator: 21 CFR. 862.1225, Creatinine Test System

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

Osteomark NTx POC for prescription (Rx) home-use is substantially equivalent to Osteomark NTx POC for professional-use. The only two differences between the two products are the intended use and the labeling. Both products share the same unitary device, procedural steps, and analytical performance.

Description of Device (21 CFR 807.92 (a)(4))

The NTx POC device is a single-use, disposable four-channel reflectance photometer integrated with dry reagent chemistry strips and contained within a sealed plastic case. The reagent strips combine capillary transport with various chemical reactions. The first strip is a lateral flow immunoassay for measuring the NTx, and the second strip is a general chemistry assay for measuring the creatinine. In both strips, a blue color is measured in discrete test zones. The test zones are the areas where specific reactions occur and concentrations are measured.

The LEDs and silicon photodetectors compare the reflectance (color intensities) of each zone before and after the addition of sample. A reference photodetector collects light directly from each LED, thus providing a correction for any variation in LED output intensity. Based on calibration parameters stored in the memory of the microprocessor, the numerical concentrations of NTx and creatinine are calculated. Assay results are expressed in nM Bone Collagen Equivalents (BCE) divided by mM creatinine (nM BCE/mM creatinine).

The NTx POC for Prescription Home-Use test contains:

- one foil pouch containing (1) NTx POC device and (1) urine dropper
- one package insert
- one urine sample cup

Intended Use (21 CFR 807.92 (a)(5))

Osteomark® NTx Point-of-Care for prescription home-use is a urinary assay for the quantitative measure of the excretion of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine).

Osteomark® NTx Point-of-Care for prescription home-use is used by lay users, under the direction of their physicians, to monitor bone resorption changes following initiation of antiresorptive therapy.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between Osteomark NTx POC for Rx home-use and the predicate device (Osteomark NTx POC for professional use) follows.

Comparison Table of Characteristics:
Similarities and Differences Between NTx POC for Rx Home-Use and NTx POC for Professional-Use

CHARACTERISTIC	NTx POC for Rx Home Use	NTx POC for Professional Use (K984530, K992997)
Intended Use	Quantitative measure of the excretion of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine).	Quantitative measure of the excretion of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine).
Indications for Use	Used to monitor bone resorption changes following initiation of antiresorptive therapy (e.g., hormone replacement therapy).	Used to monitor bone resorption changes following initiation of antiresorptive therapy (e.g., hormone replacement therapy).
Risk to Patient	Not a critical analyte - reflects the effect of antiresorptive therapy over time	Not a critical analyte - reflects the effect of antiresorptive therapy over time
Sample	Urine	Urine
Visual Display	LCD readout	LCD readout
Calibration	Not required by end-user; each unit is factory calibrated	Not required by end-user; each unit is factory calibrated
Methodology	Immunoassay (NTx) and routine chemistry (creatinine)	Immunoassay (NTx) and routine chemistry (creatinine)
Detection Method	Four-channel reflectance photometer	Four-channel reflectance photometer
Testing Environment	**Prescription home use**	**Professional use**
Throughput	5 minutes per sample - can run multiple samples simultaneously	5 minutes per sample - can run multiple samples simultaneously
Procedural Step(s)	Unmeasured urine applied directly to sample port	Unmeasured urine applied directly to sample port
Package Insert (Labeling)	**Directed towards consumer environment**	**Directed towards physician's office environment**

Brief Discussion of Nonclinical and Clinical Data (21 CFR 807.92(b)(1,2))

Nonclinical Data: Studies showed that the analytical sensitivity of the uncorrected NTx assay is 30 nM BCE, while the sensitivity of the creatinine assay is 1 mM. The Osteomark NTx POC assay did not show interference from increased levels of various biological compounds, therapeutic agents, and common micro-organisms found in urine samples. The uncorrected NTx assay is linear between 30 and 1300 nM BCE, and the creatinine assay is linear between 1 and 30 mM.

Clinical Data: Clinical studies with 220 lay consumers demonstrated Deming regression statistics as follows: $y = 0.93x + 1.9$ (x = results obtained by trained individuals. The bias at the 35 nM BCE/mM creatinine diagnostic cutoff level calculated to 34 nM BCE/mM creatinine (less than 3%).

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The nonclinical and clinical performance data from the above-mentioned studies confirm that the product is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 0 2001

Ms. Nancy J.S. Mallinak
Vice President Clinical and Regulatory Affairs
Ostex International, Inc.
2203 Airport Way South – Suite 400
Seattle, WA 98134

Re: 510(k) Number: K011052
Trade/Device Name: Osteomark® NTx POC for Rx Home-Use
Regulation Number: 862.1225, 862.1400
Regulatory Class: II
Product Code: JFY
Regulatory Class: I, reserved
Product Code: JMM
Dated: April 5, 2001
Received: April 6, 2001

Dear Ms. Mallinak:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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 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

STATEMENT OF INTENDED USE

510(K) Number (if known): K011052

Device Name: Osteomark® NTx POC for Rx Home-Use

Indications for Use:
Osteomark® NTx Point-of-Care for prescription home-use is a urinary assay for the quantitative measure of the excretion of cross-linked N-telopeptides of type I collagen (NTx) normalized to urinary creatinine (nM Bone Collagen Equivalents/mM creatinine).

Osteomark® NTx Point-of-Care for prescription home-use is used by lay users, under the direction of their physicians, to monitor bone resorption changes following initiation of antiresorptive therapy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011052

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over –the-Counter Use ___
(Per 21 CFR 801.109)