

K984285

MAY 19 1998

## 510(k) Summary

### OsteoGram® 2000

Common/Classification Name: Bone Densitometer, 21 CFR 892.1170

CompuMed, Inc.  
1230 Rosecrans Avenue  
Manhattan Beach, CA 90266

Contact: David Edelstein, Prepared: December 1, 1998

#### A. LEGALLY MARKETED PREDICATE DEVICES

The modified OsteoGram® 2000 device is substantially equivalent to the currently marketed OsteoGram device. The OsteoGram is a pre-Amendments device.

#### B. DEVICE DESCRIPTION

The use of the currently marketed device involves exposures and processing of ordinary x-rays of the hand and scanning and analysis of those x-rays at a central processing lab. The present 510(k) is for a modification to the device, one that would allow the analysis of the x-rays at the same hospital or clinic where the x-rays were taken using off-the-shelf scanner and computer equipment. The proposed device is basically a change in software to provide user help and enhanced records keeping capability.

#### C. INDICATIONS FOR USE

The OsteoGram 2000 is indicated for use in estimating bone mineral density (BMD). The estimate of BMD and t-score may be used as an aid to the physician in determining fracture risk, and for monitoring changes in bone mass over time.

#### D. SUBSTANTIAL EQUIVALENCE SUMMARY

The OsteoGram 2000 has the same indications for use as the currently marketed device. The OsteoGram 2000 has the same technological characteristics as the predicate device. However, the

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characteristics may not be sufficiently precise to assure equivalence. Therefore, CompuMed has carried out validation and performance testing. The results of this testing demonstrate that the modified OsteoGram 2000 performs as well as the currently marketed device.

**E. TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the modified device are very similar to those of the currently marketed device. The only difference is that the analysis software has been modified to provide on-line help and improved patient records management. This allows the OsteoGram x-rays to be processed at the site where they are made.

**F. TESTING**

CompuMed carried out performance testing that compared the results of the scanning and analysis of several patient hand x-rays by both naïve operators and central lab operators. The precision and accuracy of the results from the two groups of operators were almost identical.

**G. CONCLUSIONS**

The validation studies have demonstrated that the modified OsteoGram 2000 device is substantially equivalent to the currently marketed OsteoGram device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 19 1999

Compumed, Inc.  
C/O T. Whit Athey, Ph.D.  
Senior Consultant  
C.L. McIntosh Associates, Inc.  
Medical & Regulatory Affairs Services  
12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

RE: K984285  
OsteoGram 2000 Bone Densitometer  
Dated: March 17, 1999  
Received: March 17, 1999  
Regulatory Class: II  
21 CFR 892.1170/Procode: 90 KGI

Dear Dr. Athey:

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.

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) 594-4613. 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/cdrf/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K984285

Device Name: OsteoGram<sup>®</sup> 2000 Bone Densitometer

Indications For Use:

The OsteoGram 2000 is indicated for use in estimating bone mineral density (BMD). The estimate of BMD and t-score may be used as an aid to the physician in determining fracture risk, and for monitoring changes in bone mass over time.

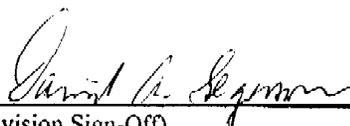
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Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K984285