

2/18/99

K984178

**510(K) SUMMARY
Pronosco X-posure System™**

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Submitter: Pronosco
Torsana Osteoporosis Diagnostics A/S
Torsana Park, Kohavevej 5
DK-2950 Vedbaek
Denmark

Contact Persons: Svenn Poulsen, MD, MBA, MFPM
Managing Director

Telephone number: (011) 45 45 65 06 00
Facsimile: (011) 45 45 65 06 06

Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Telephone number: (202) 637-5794
Facsimile: (202) 637-5910

Date Prepared: November 18, 1998

Name of Device and Name/Address of Sponsor

Pronosco X-posure System™ Bone Densitometer

Sponsor: Pronosco
Torsana Osteoporosis Diagnostics A/S
Torsana Park, Kohavevej 5
DK-2950 Vedbaek
Denmark

Telephone number: (011-45) 45 65 06 00
Facsimile: (011-45) 45 65 06 06

Common or Usual Name

Pronosco X-posure System™

Classification Name

Bone Densitometer

Predicate Devices

1. Hologic, Inc.'s QDR 2000 X-Ray Bone Densitometer (K913321)
2. Norland Medical Systems' Norland 178 Bone Mineral Analyzer (preamendments device)
3. Norland Medical Systems' pDEXA® Bone Densitometer with Fracture Risk Assessment Option (K973104)
4. Compumed, Inc.'s Osteogram (preamendments device)

Intended Use

The Pronosco X-posure System™ is intended for use to estimate BMD in the forearm and to assess increased risk of osteoporotic fractures according to World Health Organization ("WHO") criteria. The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (*i.e.*, prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); and (2) compare the BMD estimate with reference populations of young normals and age matched normals to compute T-scores and Z-scores, respectively. All of the predicate devices are also intended for use in BMD estimation, and several are intended for use to estimate fracture risk. The specific indications for use of the Pronosco X-posure System™ are also substantially similar to the predicates.

Principles of Operation

The Pronosco X-posure System™ estimates BMD based on established principles of radiogrammetry. A standard x-ray is first scanned into the system, then analyzed by computer to assess cortical thickness and textural characteristics in the pre-defined region of interest, which consists of the radius, the ulna, and the second through fourth metacarpals. The BMD estimate may be compared to a reference database of young normals and age matched normals to compute T-scores and Z-scores, respectively.

Technological Characteristics

The Pronosco X-posure System™, the Hologic QDR-2000, the Norland Model 178, the Norland pDEXA®, and the Compumed Osteogram all provide estimates of BMD to aid the physician in diagnosing osteoporosis. While the Pronosco X-posure System™ derives the BMD estimate based on radiogrammetric principles, rather than absorptiometry methods, this approach does not raise any new questions of safety or effectiveness, because the Compumed Osteogram similarly derives BMD estimates from computerized analysis of radiographic images. In addition, all of the devices determine forearm BMD using similarly defined regions of interest, and several of the devices use similar methods to analyze fracture risk. Clinical testing and performance testing have also demonstrated the safety and effectiveness of the Pronosco X-posure System™ for this intended use.

Summary Basis for the Finding of Substantial Equivalence

The Pronosco X-posure System™ has substantially the same intended use and indications for use as the predicate devices. In addition, the minor differences in the technical characteristics of the devices, such as differences in the BMD estimation method or the precise regions of interest used to determine forearm BMD, do not raise new questions of safety or effectiveness, as confirmed by clinical and performance testing. Thus, the devices are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jonathan S. Kahn, Esq
C/o Hogan & Harston, LLP
Torsana Osteoporosis Diagnostics A/S
555 13th Street, N.W.
Washington, DC 20004

Re: K984178.
Pronosco X-posure System™
Dated: November 20, 1998
Received: November 20, 1998
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Kahn:

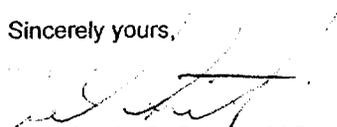
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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/cdrh/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

510(k) Number (if known): _____

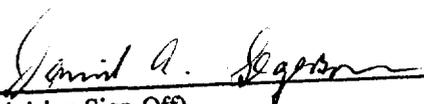
Device Name: Pronosco X-posure System™

Indications For Use:

The Pronosco X-posure System™ is intended for use to estimate BMD in the forearm and to assess increased risk of osteoporotic fractures according to World Health Organization ("WHO") criteria. The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (i.e., prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); and (2) compare the BMD estimate with reference populations of young normals and age matched normals to compute T-scores and Z-scores, respectively.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984178

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)