K091325

NORLAND
a CooperSurgical Company

W6340 Hackbarth Road / Fort Atkinson, WI 53538
(920) 563-9504 / Fax (920) 563-8626

510(k) Summary

prepared in accordance with 21 CFR Part 807.92(c)
April 2009

JUN 29 2009

1. Name
   Ten-Year Fracture Risk and SIRI Table Options for Norland DXA Bone Densitometers

2. Manufacturer
   Norland, a CooperSurgical Company
   W6340 Hackbarth Road
   Fort Atkinson, WI, 53538
   Establishment Registration #2124648

3. Owner
   Cooper Surgical Inc.
   95 Corporate Drive
   Trumbull, CT, 06611
   Establishment Registration #1216677

4. Contact Person
   Mr. Tom Williams
   VP RA/Business Assurance

5. Trade Name
   Ten-Year Fracture Risk and SIRI Table Options for Norland DXA Bone Densitometers

6. Common Name
   Ten-Year Fracture Risk and SIRI Table Options

7. Classification
   DXA Bone Densitometer, 90 KGI, Class II, Section 892.1170

8. Predicate Device Comparison
   Ten-Year Fracture Risk Option
   K080711, Hologic 10-year Fracture Risk Questionnaire Option.
   The Norland Ten-Year Fracture Risk Option is substantially equivalent to the Hologic 10-year Fracture Risk Option. Both use the World Health organization (WHO) Fracture Risk Assessment algorithm (FRAX) to estimate the patient's risk of hip fracture and major osteoporotic fracture. No new safety or efficacy questions are raised.

   SIRI Table Option
   K071570, GE Lunar Body Composition Software Option.
   K014009 – Tanita Body Composition Analyzer
   The Norland SIRI Table Option for the Norland DXA Bone Densitometers is substantially equivalent to the GE Lunar Body Composition Software Option. Both use DXA technology to determine % Body Fat, and both plot this value against the gender and age matched Body Fat Charts to indicate if the patient is Underfat, Healthy, Overfat, or Obese. Further, both use similar technology and have similar intended uses. The SIRI Table Option is also comparable to the

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Tanita Body Composition Analyzer because it uses the relationship between % body fat and the classifications (Underfat to Obese), that was developed by Tanita and used in their analyzer. No new safety or efficacy questions are raised.

9. Device Description

The Ten-Year Fracture Risk Option and the SIRI Table Option for the Norland DXA Bone Densitometers are software options that use presently provided scan results and related industry standards to provide additional information to the medical professional as they diagnose and treat bone related and body fat related diseases and conditions.

10. Intended Use

The Ten-Year Fracture Risk Option uses the femoral neck T-Score results of the Norland DXA bone densitometer, along with the results of a Clinical Risk Factor questionnaire, to determine the patient's risk of incurring a hip fracture or a major osteoporotic fracture in the next ten years. This information is useful to health care professional as they manage diseases or conditions relating to bone health. This option does not diagnose disease or recommend treatment.

The SIRI Table Option uses the SIRI UWE % Fat results of the Norland DXA bone densitometer to classify the patient as Underfat, Healthy, Overfat, or Obese, based on the industry standard Body Fat Charts developed by Tanita from the work done by D. Galligher. It also calculates the industry standard BMI based on the patient height and weight information entered by the operator. This information is useful to health care professionals as they manage diseases or conditions relating to or affected by the patient's relative amount of fat tissue. This option does not diagnose disease or recommend treatment.

11. Technological Characteristics

These options do not affect the technology of the Norland bone densitometers. No physical changes are required and the scanning and analysis functions are not impacted. They only require software modifications to add their additional features.

12. Non-Clinical Tests

Ten-Year Fracture Risk:

The chart values in the software were compared to the values in the charts on the FRAX website, by a person different from the one who entered the data. The clinical risk factors and the low, moderate, and high significance assigned to them, were verified to be the same as the FRAX publication.

Previously acquired data from 150 patients was used by the new software to generate their Ten-Year Probability of a hip fracture and of a Major Osteoporotic Fracture. These values were then compared to the values given by the charts on the FRAX website for the same demographics. The results correlated well and a linear regression analysis was carried out on the resulting data.

SIRI Table Option:

Previously acquired data from 150 patients was used by the new software to generate their bone exam report, to verify the proper chart was included in the report, and to verify the SIRI UWE % Fat value was properly plotted on the chart.

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13. Clinical Tests
Clinical testing was not required for either of these options to establish safety or effectiveness. because they do not cause changes to the scanning or analysis processes. Instead, they just use the values presently generated to produce their results.

However, proper operation of both options with real patient data was tested, using sets of clinical data available from Norland customers. See bench testing above. However, no subjects were scanned solely to test these new options.

14. Test Conclusions
Testing confirms the performance of the Ten-Year Fracture Risk Option and the SIRI Table Option is consistent with the indications for use; and that these options are substantially equivalent to currently marketed devices with respect to safety and efficacy.

15. Other Pertinent Information
(None)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Mr. Thomas G. Williams
VP RA/Business Assurance
CooperSurgical, Inc.
95 Corporate Drive
TRUMBULL CT 06611

Re: K091325
Trade/Device Name: Ten-Year Fracture Risk and SIRI Table Option for Norland DXA Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: April 30, 2009
Received: May 5, 2009

Dear Mr. Williams:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091325

Device Name: **Ten-Year Fracture Risk and SIRI Table Options for Norland DXA Bone Densitometers**

Indications for Use:*

Ten-Year Fracture Risk Option

The Ten-Year Fracture Risk Option for the Norland DXA Bone Densitometeters uses the femoral neck T-Score, along with certain clinical risk factors, to estimate the patient's ten-year risk of a hip fracture and/or a major osteoporodic fracture, based on the FRAX algorithm developed by the World Health Organization (WHO). This information is useful to health care professional as they manage diseases or conditions relating to bone health. This option does not diagnose disease or recommend treatment.

SIRI Table Option

The SIRI Table Option for the Norland DXA Bone Densitometers uses the SIRI UWE % Fat value, and plots it on the industry standard body fat charts. The chart used depends on the patient's gender and age, and it indicates whether the patient is Underfat, Healthy, Overfat, or Obese. These charts are the result of work done by the National Institute of Health (National Heart, Lung, and Blood Institute), who assigned underfat to obese classifications to the BMI value; and by Tanita Corporation, who related BMI to % body fat based on DXA bone densitometry. This option also calculates the patient's Body Mass Index (BMI) based solely on the height and weight data inputted by the operator, as a convenience. This information is useful to health care professional as they manage diseases or conditions relating to or affected by the patient's relative amount of fat tissue. This option does not diagnose disease or recommend treatment.

Prescription Use ___YES___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___NO___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Center for Devices and Radiological Health / CDRH

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091325