MAR 2 2 2011

510(K) Summary, K093046

Synvasive Technology, Inc.
4925 Robert J. Mathews Pkwy
El Dorado Hills, CA 95762
Phone: 916-939-3913
Contact: Michael G. Fisher
Date prepared: April 7, 2010

1. **Trade Name: eLibra® Uni Soft Tissue Force Sensor**
   Common Name: Intraoperative orthopedic joint assessment aid
   Classification Name: Stereotaxic instrument., product code ONN, Regulation: 882.4560 Class of device: Class 2.

2. **The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : K070108 eLibra Dynamic Knee Balancer, Synvasive Technology**

3. **Description of device: The device consists of two units, the force sensing unit and an electronic display. The eLIBRA® Uni Soft-Tissue Force Sensor for a Partial Knee Replacement is a single use battery powered device designed to transmit an electronic signal to the eLIBRA™ Display Unit. The eLIBRA Display Unit is a reusable battery powered device designed to receive an electronic signal from the eLIBRA® Uni Force Sensing Unit. The unit displays a number from 0-19 for both the for flexion and extension positions of the knee joint to aid the surgeon in developing a balanced implantation during a primary unicondylar knee arthroplasty (UKA). Each number is equivalent to 0.5 pounds of force.**

4. **Intended use: The eLIBRA® Display Unit is a reusable battery powered device designed to receive an electronic signal from the eLIBRA® Uni Soft-Tissue Force Sensor for Partial Knee Replacement. The unit displays a number from 0-19 for flexion and extension positions of the knee joint to aid the surgeon in developing a balanced implantation during a primary unicondylar knee arthroplasty (UKA). The force sensor is sterile, for single patient use.**

5. **Technological characteristics: The technological characteristics are essentially identical to our predicate device.**

6. **Performance: Both bench and test laboratory testing was performed. Bench testing included mechanical testing, radio frequency, and sterility testing, including EO residues. The results were satisfactory and revealed no concerns over safety and effectiveness as compared to our predicate device. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Synvasive Technology, Inc.
% Kamm & Associates
Mr. Daniel Kamm
8870 Ravello Court
Naples, Florida 34114

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Re: K093046
Trade/Device Name: eLibra Uni Soft Tissue Force Sensor
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: ONN
Dated: February 28, 2011
Received: March 4, 2011

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093046

Device Name: eLibra Uni Soft Tissue Force Sensor

Indications For Use:

The eLIBRA® Display Unit is a reusable battery powered device designed to receive an electronic signal from the eLIBRA® Uni Soft-Tissue Force Sensor for a Partial Knee replacement. The unit displays a number from 0-19 for flexion and extension positions of the knee joint to aid the surgeon in developing a balanced implantation during a primary unicondylar knee arthroplasty (UKA). The force sensor is sterile, for single patient use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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