K112121

ergoline

OCT 3 1 2012

510(k) Summary

>> 510(k) Summary as required by section 807.92(c)

Submission Applicant:
Ergoline GmbH
Lindenstrasse 5
72475 Bitz / Germany
Establishment Registration Number: 3005438755

10/22/2012

Application Correspondent/Contact:
think!
Andrea Pecsi
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78532 Tuttlingen
Germany
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Common name: Exerciser

Classification name:
Measuring exerciser
> 21 CFR – 890.5360 Measuring exercise equipment

Product Code: ISD

Trade name: Ergoline Ergoselect / GE

Predicate Device:
K-number: K053078
Device name: Ergoselect 100 K/P; Ergoselect 200 K/P
Firm: Ergoline GmbH

Description of the Device:

The Ergoselect is the result of long-standing experience and its consequent implementation. The system is convincing thru the optimal, and therefore, cost-effective configuration of the ergometer according to in medical ergometer specific requirements.
Modern computer control allows Stand-alone operation of the ergometer as well as comfortable control via external devices (PC system).

Ergoline Ergoselect / GE measures data concerning patients procedures and in conjunction with ergometer bicycles procedures.

Ergoselect / GE ergometer includes following models (P/K versions):
Ergoselect 50
Ergoselect 100 / 200
Ergoselect 600
Ergoselect 1000
Ergoselect 1200
Optibike 50 med
Optibike med

Indications for Use:

Physiotherapy in redevelopment of muscles for restoration of motion to joints or for use as an adjunct treatment for obesity.

Technological characteristics compared to the Predicate Device:

The features of the subject device are substantially equivalent to the predicate device based on similarities in terms of design, operational, configurational, ergometrical, technical and safety characteristics. In addition, the classification and intended use of the predicate and subject device are the same.
The Ergoselect / GE ergometer can be deemed substantially equivalent and safe and effective for its indicated use.

Non-clinical performance data:

Ergoline certifies compliance with the requirements among others of following device relevant standards: IEC 60601-1: Medical Electrical Equipment, General Requirements for Safety; IEC 60601-1-2: Medical Electrical Equipment, General Requirements for Safety, Electromagnetic compatibility – requirements and tests; ISO 14971: Medical devices -- Application of risk management to medical devices; and ISO 10993 Biological evaluation of medical devices.

Summary:

The presented data that was conducted on the Ergoline / GE ergometer shows in its results and in comparison that the products perform as well as or better than the predicate device, safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for years with no device failures. The used materials are well researched and do not raise new questions regarding safety and effectiveness of the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ergoline GmbH
% Ms. Andrea Pecsi
Schwarzwaldstrasse 5
Tuttlingen, BW
78532, Germany

OCT 31 2012

Re: K112121
Trade Name: Ergoselect / GE
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring exercise equipment
Regulatory Class: Class II
Product Code: ISD
Dated: October 22, 2012
Received: October 26, 2012

Dear Ms. Pecsi:

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 Statement

510(k) Number (if known): K112121

Device Name: **Ergoline Ergoselect / GE**

Indications for Use:

Physiotherapy in redevelopment of muscles for restoration of motion to joints or for use as an adjunct treatment for obesity.

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

(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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K112121