K053078

Summary of Safety and Effectiveness

1.) Submission Applicant & Correspondent

Name: **Ergoline GmbH**
Lindenstr. 5
72475 Bitz/Germany

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Mail: info@bell-qm.de

Contact person : Haiko Bell

APR 27 2006

2.) Device name & Classification panel

Trade name: Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P

Common name: Ergometer

Classification: 890.5360

3.) Substantial Equivalence:

Substantial Equivalence is claimed to the following device

K851097

4.) Description of device

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

The Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P ergometer has been designed to meet the medical and ergonomic requirements
for an efficient and relevant stress test of the cardiovascular system. Modern computer control allows Stand-alone operation of the ergometer as well as comfortable control via external devices (PC system). Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P ergometer measures data concerning patients procedures and in conjunction with ergometer bicycles procedures.

Material:
PPSU – Polyphenylsulfon – BODY
Stainless Steel – ST37K- yellow zinced- FRAME/SADDLE TUBE/SADDLE GUIDE TUBE
Polyol, Isocyanate, Emerald leather – SADDLE

Cardiac monitor (in compliance with Recognized Consensus standard AAMI/ANSI EC13:1992, Cardiac monitors, heart rate meters, and alarms):
Control head type K offers the possibility of measuring the heart rate via an integrated receiver and a chest belt for the patient. QRS Signals/data are radio transmitted from the chest belt to the control head type K receiver. Identification of the chest belt takes 10 seconds. The current heart rate of the patient is then indicated and updated at the control head. The chest belt is switched on automatically as soon as sufficient contact between the two contact areas is established.

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Exercised Muscles:
- Front of thighs
- Quadriceps
- Backer Thighs (hamstrings)
- Pelvis
- Gluteal muscles
- Calfs
- Gastrocnemius
- Soleus

Exercised Joints:
- Hip extensor
- Hip flexor
- Knee extensor
- Knee flexor
- Ankle plantar flexor

The ergometry system Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P consists out of the following components:

Basic unit:	Ergoselect 100; Ergoselect 200
Control unit:	Control panel type P / K

Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P ergometer measures data concerning patients procedures and in conjunction with ergometer bicycles procedures.

5.) Intended Use & indications:

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

6.) Summary of Technological Characteristics:

The implemented technology of the Ergoline Ergometers is identical or similar following the Substantial Equivalence comparison rational. No technical characteristics in terms of similiarity/differences are existing that would raise new questions regarding safety and effectiveness.

7.) Conclusion:

Based upon the information presented within this Premarket Notification and summarized above, it is concluded that the Ergoline Ergometers are safe and effective for their Intended Use and that Substantial Equivalence is verified and justified in comparison to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Ergoline GmbH
c/o Mr. Stefan Preiss
510 (K) TPR Program Manager
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K053078
Trade/Device Name: Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring exercise equipment
Regulatory Class: II
Product Codes: ISD
Dated: April 6, 2006
Received: April 12, 2006

Dear Mr Preiss:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K053078

Device Name: Ergoline Ergoselect 100 K/P; Ergoselect 200 K/P

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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053078