King Fisher Healthcare
Technology for Life

MAR 11 2008

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Interleuvenlaan 62
Leuven
Belgium, 3001
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"510(k) Summary"
As required by 21 CFR 807.92

Owner's Name

Kingfisher Healthcare NV

Address:

Interleuvenlaan 62
Leuven
3001
Belgium

Telephone Number:	+32 16 39 78 37
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Contact Person	Sally Sennitt, MD, Medical Director

Summary Prepared

Date	December 4, 2007

Classification name

Transcutaneous electrical nerve stimulator for pain relief

Product Code	84 GZJ
Regulation	21 CFR 882.5890

Common/Usual Name

KFH Energy model E1

Proprietary Name

Kingfisher Healthcare NV KFH Energy model E1

Establishment Registration Number

The device will be manufactured by

Kingfisher Healthcare NV
Interleuvenlaan 62
Leuven
B-3001 Belgium
Telephone +32 16 39 78 37
Fax +32 16 39 78 41
Establishment Registration Number: to be applied for

and

Fela Leiterplattentechnik GmbH
Sturmbuehlstrasse 180
VS Schwenningen
D-78056 Germany
Telephone +49 7720 39 02 30
Fax +49 7720 39 02 70
Establishment Registration Number: to be applied for

Fela Leiterplattentechnik GmbH is identified for completeness, however they are a supplier to Kingfisher Healthcare NV and not a Contract Manufacturer. Fela Leiterplattentechnik GmbH perform only certain agreed operations on instructions from Kingfisher Healthcare NV and deliver product for acceptance only to Kingfisher Healthcare NV.

Substantial Equivalence:

The Kingfisher Healthcare NV KFH Energy model E1 is substantially equivalent in design, use and materials to the:

Electromedical Products Intl Inc, Alpha Stim
K896948, K881753, K831145, K831144
BioMedical Life Systems, Electro-nerve stimulator TENS model micro plus-A
K915210
Lhasa Oms Inc, E Stim II
K050435
Fuji Dynamics Ltd, Medisana Digital Tens
K994265
Globalcare Intl., Inc, Globalcare Micro II and Microcare (TENS)
K903394

Comparison of Technological Characteristics

The Kingfisher Healthcare NV KFH Energy model E1 is a microcurrent TENS device for pain relief with an output similar to that of the above referenced legally market products. The Kingfisher Healthcare NV KFH Energy model E1 differs from some of the above products in that it is a dedicated microcurrent device and does not have a high-current mode.

The Kingfisher Healthcare NV KFH Energy model E1 is made of the same types of material as the products referenced above. The front display of the Kingfisher Healthcare

NV KFH Energy model E1 differs from the predicates in that it is made of a "wipe-clean" glass surface eliminating any possibility for contamination to build up around indicators or controls.

Patient Contact

Patient contact with the main device is limited to finger operation of the controls and made only with glass front panel or ABS casing (when held in the hand). Connection to the patient is made by electrodes which are already legally marketed:

Electrodes:	Top-Rank Healthcare Equipment Co Ltd Adhesive Electrode K070612
Gel:	Sekisui Plastic Co Ltd Technogel, included in electrodes above K070612

Description of Product:

The Kingfisher Healthcare NV KFH Energy model E1 is built in an ABS casing with controls and indicator integrated into a touch-sensitive opaque glass front panel, and designed to be comfortably held in the hand.

The approximate dimensions of the unit are 190 x 80 x 30 mm and complete with batteries the unit weighs approximately 350 g (including batteries).

The device is designed to deliver electric current in the range 300 to 600 microamperes at 100 Hz frequency to the body from four "AA" sized batteries (contained internally), for a predetermined time (30 or 60 minutes), through four adhesive skin electrodes (already found substantially equivalent through the 510(k) process). The output waveform is monophasic, rectangular with decay.

Housing

The ABS plastic housing is comprised of three parts:

- upper housing
- lower housing, and
- battery compartment cover

The battery compartment cover is a clip fit to the lower housing, secured with a screw, which is sealed to the upper housing with a rubber gasket and retained in position by four screws. Two electrical connectors are located in the housing, identified as C1 (channel 1) and C2 (channel 2), for connection of the four patient contacting electrodes.

Glass Front Panel

The front glass panel is opaque and sealed to the upper housing by a self-adhesive gasket. Electrical circuitry is integrated into the rear of the glass panel allowing the front face to act as a "touch-sensitive" user interface. Two depressions are milled into the front face of the glass front panel to assist locating the fingers over the control areas:

- a circular depression over the on/off control
- a "ring" shaped depression over the output control area. The two sides of the "ring" can be used to independently control the two output channels.

The electrical circuitry also contains the status indication light emitting diodes which can be seen through the glass panel:

- power on
- low battery warning
- an output set-point indicator for each channel
- six "count-down" timer indicators (10, 20, 30 ,40, 50 and 60 min.)

Controller Board

A controller board is located between the upper and lower housings. This is the FR4 based current generator rated at: 0 – 33 v d.c., 400 µA, 100 Hz.

The Kingfisher Healthcare NV KFH Energy model E1 will be packaged in a presentation cardboard case together with electrodes, leads, batteries, storage bag and the user manual.

The KFH Energy device is indicated for the symptomatic relief of:

- Chronic Intractable Pain
- Post-Traumatic Pain

- Post-Surgical Pain

Testing:

Non-Clinical Testing

The following non-clinical testing has been included in the premarket notification to demonstrate substantial equivalence to the predicate device and meet the guidance in FDA's August 1994 "Guide for TENS 510(k) Content":

- Enclosure materials testing
- Battery life testing
- Device extended use reliability testing
- Firmware functional performance
- Device functional performance
- Functional testing to product specification
- Connection testing

Clinical Testing Submitted

No clinical testing is included.

Summary of Testing:

From the above testing, Kingfisher Healthcare NV concludes that the KFH Energy Model E1 is substantially equivalent to the predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kingfisher Healthcare NV
% MeddiQuest Limited
Mr. Neil R. Armstrong
Business & Technology Center
Bessemer Drive
Stevenage
Hertfordshire SG1 2DX
United Kingdom

MAR 11 2008

Re: K073008
Trade/Device Name: KFH Energy Model E1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: February 28, 2008
Received: March 3, 2008

Dear Mr. Armstrong:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

King Fisher Healthcare
Technology for Life

Indications for Use

510(k) Number (if known): _K073008_

Device Name: _ The Kingfisher Healthcare NV, KFH Energy model E1

Indications for Use:

The KFH Energy device is indicated for the symptomatic relief of:

- Chronic Intractable Pain
- Post-Traumatic Pain
- Post-Surgical Pain

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxn

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

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(Posted November 13, 2003) **510(k) Number** K073008