Certificate No FM20708

OAKFIELD INSTRUMENTS LTD

HEALTH CARE PRODUCTS

Oakfield Industrial Estate,
Stanton Harcourt Road, Eynsham,
Witney, Oxon, OX8 1JA
Tel: (+44) 1865 882532
Fax: (+44) 1865 883970

Re: FDA 510(K) Submission - FLEXILOG LS Esophageal Sphincter Detector D

510K SUMMARY

Oakfield Instruments Limited,
Oakfield Industrial Estate,
Stanton Harcourt Road,
Eynsham, WITNEY,
Oxfordshire, OX8 1JA,
United Kingdom.

TEL: (+44) 1865 882532

FAX: (+44) 1865 883970

John Giddings, Sales & Marketing Manager

20th November 1996

Trade Name: FLEXILOG LS

Common Name: Esophageal Sphincter Detector

Classification Name: Monitor, esophageal motility and tube

Substantial equivalence is claimed to the following devices:

Oakfield Instruments Limited, Oakfield Industrial Estate, Stanton Harcourt Road, Eynsham, WITNEY, Oxfordshire, OX8 1JA	FLEXILOG LS
Sandhill Medical Inc, 8955 South Ridgeline Blvd #500, Highlands Ranch, CO 80126, U.S.A.	RMS III The LES Locator Biolab
Synectics Medical Limited, 215 Willow Road, ENFIELD, Middlesex, EN1 3BT.	Digitrapper MKIII Digitrapper MD PC Polygraph HR

Description

The FLEXILOG LS is a single channel, pressure monitoring system comprising of a module of electronics that provides transducer excitation, amplification, digitisation and transmission of the signal to a computer via an optically isolated RS232 connector. The pressure signal is displayed on the computer VDU via a Microsoft Windows display program. The program does not provide any analysis or data saving options.

The electronics module is designed to be compatible with catheter tip perfused pressure transducers currently available in the US market.

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Indications

The FLEXILOG LS is used for the location of the lower and/or upper esophageal sphincter and the measuring of the nares to esophageal sphincter distance. This procedure being carried out prior to the accurate placement of a pH sensitive catheter for an ambulatory pH study to quantify gastroesophageal reflux.

Technological Characteristics

The FLEXILOG LS is a single channel pressure system similar to those in the predicate devices; FLEXILOG LS Lower Esophageal Sphincter Detector, RMS III, the LES Locator, Digitrapper MKIII and Digitrapper MD. However, the electronics are contained in a standalone box, not contained with the ambulatory pH recorder box as in the RMS III, Digitrapper MKIII and Digitrapper MD. Nor does it require to be connected to a pH recorder as does the LES locator. Pressure data is displayed on a computer screen as with the multi channel Biolab and PC Polygraph HR systems.

Testing

The FLEXILOG LS has been shown to accurately measure and display pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Giddings
Sales Manager
Oakfield Instruments Ltd.
Oakfield Industrial Estate
Stanton Harcourt Road, Eynsham
Witney, Oxon, OX8 1JA
UNITED KINGDOM

AUG - 6 1997

Re: K964804
FLEXILOG LS Oesophageal Sphincter Detector
Dated: May 2, 1997
Received: May 9, 1997
Regulatory class: II
21 CFR §876.1725/Product code: 78 KLA

Dear Mr. Giddings:

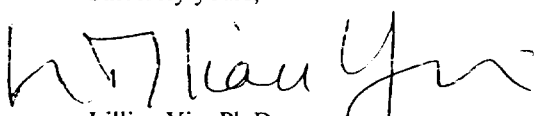
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: FLEXILOG LS OESOPHAGEAL SPHINCTER DETECTOR

Indications For Use:

The FLEXILOG LS, Esophageal Sphinctor Locator, is to be used for the manometric location of the lower and upper esophageal sphincters. That is the measurement of the distance from the nares to the sphincter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964804

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)