



OAKFIELD INSTRUMENTS LTD

NOV 4 1996 HEALTH CARE PRODUCTS

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Stanton Harcourt Road, Eynsham,
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K961895

Re: 510K Submission - FLEXILOG LS, Lower Esophageal Sphincter Detector D

510K SUMMARY

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John Giddings, Sales & Marketing Manager

13th May 1996

Trade Name: FLEXILOG LS

Common Name: Lower Esophageal Sphincter Detector

Classification Name:

Substantial equivalence is claimed to the following devices:

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 and water perfused pressure transducers currently available in the US market.



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-2-

Indications

The FLEXILOG LS is used for the location of the lower esophageal sphincter and the measuring of the nares to lower 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 measuring system similar to those in the predicate devices RMS III, the LES Locator, Ditrappet MK III and Ditrappet MD. However, the electronics are contained in a standalone box, not contained within the ambulatory pH recorder box as in the RMS II, Ditrappet MK III and Ditrappet 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.

GP
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Tom Giddings
14/5/96