

510(k) SUMMARY

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John Giddings, Sales & Marketing Manager

28th October 1996

Trade Name: FLEXILOG 3000

Common Name: Multi Channel, Multi Parameter Recording System

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.

Superlogger

Synectics Medical Inc
1425 Greenway Drive
Irving
TX 75038, U.S.A.

MicroDigitrapper

Medical Measurement Systems
PO Box 40178
7504 RD Enschede
THE NETHERLANDS

UPS-2020

1. Description

The FLEXILOG 3000 system is a multi channel, multi parameter, ambulatory recording system with stationary capability. It is comprised of a recorder that supports data collection on up to 24 channels. The data collected is determined by up to 5 plug-in parameter modules. At present only pH (4 channel) and pressure (3 channel) modules are available. Multiple modules of the parameters can be installed to give the required number of channels.

In ambulatory mode, data is saved onto a PCMCIA card and subsequently uploaded to the computer. In stationary mode, data is transferred via a patient isolated RS232 outlet to the computers serial port. The signals, recorded or online, are displayed on the computer VDU via a Microsoft Windows based program, FLEXISOFT III.

FLEXISOFT III provides display, analysis and report generation options.

The FLEXILOG 3000 is compatible with pressure and pH catheters currently approved for sale in the U.S.A. and manufactured and marketed by third parties.

FLEXILOG 3000 Multi Channel, Multi Parameter, Recording System

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2. Indications for use

The FLEXILOG 3000 system is to be used for the recording, display and analysis of pH and pressure data from the upper gastrointestinal tract in ambulant subjects. It provides information that aids in the diagnosis and management of motility disorders. The FLEXILOG 3000 also has a limited stationary manometry capability to aid sensor placement prior to an ambulatory study.

3. Technology Characteristics

The FLEXILOG 3000 is similar to the predicate devices having both ambulatory and stationary capability; being multi channel and recording both pH and pressure data. The system differs in that the parameter electronics are modular and data is saved to a PCMCIA memory card.

Control display and analysis software are Microsoft Windows based.