MAY 12 1999

Summary of Safety and Effectiveness

Introduction

The Safe Medical Device Act (SMDA) of 1990 requires that in addition to other information submitted in a 510(k), medical device manufacturers submit a summary of information regarding safety and effectiveness for the device subject to the 510(k). The summary is to include detailed information regarding adverse health effects of the device. This Summary of Safety and Effectiveness document is intended to comply with the SMDA requirement. FDA will make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

Sandhill Scientific, Inc.
8955 S. Ridgeline Blvd., #500
Highlands Ranch, CO 80126

USA Contact Person

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Date Prepared

January 22, 1999

Trade Name of Device

InSIGHT Sphincter of Oddi Manometry Module

Common Name of Device

Sphincter of Oddi Manometry

Classification Name

System, Gastrointestinal Motility (Electrical)

510(k) Classification

Class II

Comparison to Predicate Devices

The InSIGHT Sphincter of Oddi Manometry (SOM) Module is a manometry recording device with features equivalent in safety and performance to those included on prior legally marketed devices. The InSIGHT SOM Module is Substantially Equivalent to:

K932306 Microinfuser, Manufactured by Sandhill Scientific, Inc.

K900058, Wilson-Cook Biliary Motility Catheter, Manufactured by Wilson-Cook Medical, Inc.

Pre-Amendment, Hewlett-Packard Model 7788-A, Manufactured by Hewlett-Packard Corporation.

Device Description and Intended Use

The Sphincter of Oddi Manometry Module is intended for use by Gastroenterologists or Surgeons to determine intraluminal pressures within the pancreaticobiliary ductal system and motor activity within the sphincter of Oddi zone. The InSIGHT Sphincter of Oddi Manometry Module includes analysis software, but requires skilled interpretation by a physician to make a diagnosis.

Technological Characteristics

The SOM Module is intended for use only with the InSIGHT Model S980000 Gastrointestinal Motility system (K984444). The InSIGHT system consists of three basic subsystems. These are:

Signal conditioning and recording hardware

This subsystem includes the hardware that amplifies the transduced signals for recording, provides electrical isolation for safety, and processes the signals for subsequent analysis.

Analysis software

The software displays the waveforms, shows the analyzed results and incorporates these results into reports.

Probes and transducers

These are used to generate the signal that is recorded. Sandhill does not manufacture the transducers and probes that are intended for use with the system, but these carry the manufacturers' approval to market and meet the manufacturers' safety requirements for their use.

The technological characteristics of the InSIGHT SOM Module are the same as, or perform equivalently to, the predicate devices.

Applicable Standards and Non-Clinical Testing

In compliance with the company's Design Controls procedures, the InSIGHT Model S980000 system has been designed to meet the requirements of the following standard:

UL 2601-1: *Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety*

Certification of the design to the above standards and the device design specifications is through a planned combination of internal design testing to written protocols and outside laboratories. No formal clinical testing has been performed, nor is any believed to be necessary.

Potential Adverse Health Effects

The InSIGHT SOM Module has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. One or more of the following means (in order of preference) was used to implement mitigation of health hazards identified by the risk management program:

1. Design modifications.
2. Detection of hazard conditions and alerting of the user through alarms and visual indications.
3. Identification of any potentially undetectable health hazard conditions in the instruction manual and other device labeling.

The user must be qualified in biliary diagnostic procedures, trained in the use of the system, and must be familiar with all labeling and instructions for use associated with the equipment. Many device injuries are due to user error and failure to follow the instructions for use. The user of the device is advised to thoroughly understand the use of the equipment, and familiarize themselves with the location and function of all controls and alarms prior to using the equipment.

Sandhill Scientific believes that the InSIGHT SOM Module is safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1999

Ms. Linda L. Diederich, MT-ASCP
Vice-President of Marketing & Customer Relations
Sandhill Scientific, Inc.
8955 South Ridgeline Boulevard
Unit #500
Highlands Ranch, Colorado 80126

Re: K990441
InSIGHT Sphincter of Oddi
Manometry Module, Model S981300
Dated: February 9, 1999
Received: February 11, 1999
Regulatory Class: II
21 CFR 876.1725/Procode: 78 FFX

Dear Ms. Diederich:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: InSIGHT Sphincter of Oddi Manometry Module

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990441