

510(k) Summary

K972439

P192

DRAERD 510(k)

Summary of Safety and Effectiveness Information

Submitter's name

Synectics Medical AB
Renstiernas gata 12
S-116 28 Stockholm
Sweden

Synectics Medical Inc
3850 Victoria Street North
Mail Stop V215
Shoreview, MN 55126-2978

SEP 23 1997

Contact: Anna Pettersson

Contact: Keith Jung

Name of device

Anorectal Manometry Analysis Module

Name of equivalent device

Polygram Software (DOS environment)
(included in 872712 - Polygraf)

The Anorectal Analysis Module is identical, in function and types of analyses that can be performed, to the Polygram Software (DOS). The main difference is that the Polygram Software (DOS) is written for the DOS environment and the Anorectal Analysis Module is written for the Windows environment. Polygram Software (DOS) works in the DOS environment and the Anorectal Analysis Module works in the Windows environment.

Description of device

The Polygram Software for Windows (K946322) was designed to record and handle/store physiological parameters. After a recording, the user is able to review the tracings on the computer screen and print the signal tracings or just parts of them. When reviewing the data on the computer screen, the user is able to mark certain segments and calculate certain parameters from the selected signal segments. These parameters include minimum and maximum values, length of selection.

By adding the Anorectal Analysis Module to the Polygram Software for Windows, the user can also have all the pressure data analyzed in terms of physiological properties, comparison with normal values, etc. The analyzed data can thereafter be viewed on screen or printed out on a separate paper.

The analysis report includes sections such as patient demographics; interpretation and comment (for user to insert); procedure summary; Anorectal tracing; analyses (as specified below); and physician signature section.

Analyses:

- Vector Volume Analysis
- Automatic Base Line Analysis
- Interpretation and Comments Analysis
- Rectal Balloon Analysis
- Tri-Level Analysis
- Radial Pressure Analysis
- Anal Canal Vector Volume Analysis
- Tracing Clip-Out Analysis
- Quick Calculation Analysis

The analysis report can then serve as a tool for the physician's diagnosis and post treatment evaluation.

K972439
P2072

Performance Testing

The Anorectal Analysis Module has been thoroughly tested during the development phase, that is, alpha testing in terms of integration testing has been performed and documented and beta testing in terms of hospital site testing has been done and documented.
It has been concluded that the alpha and beta testing has meet and passed the specified objectives and should therefore be released to the market.

Statement of intended use/indication for use

The Anorectal Analysis Module is a software program that has been designed to analyze pressure data recorded from the lower gastrointestinal tract in pediatric and adult populations.

The Anorectal Analysis Module includes the following analyses:

- Vector Volume Analysis
- Automatic Base Line Analysis
- Intepretation and Comments Analysis
- Rectal Balloon Analysis
- Tri-Level Analysis
- Radial Pressure Analysis
- Anal Canal Vector Volume Analysis
- Tracing Clip-Out Analysis
- Quick Calculation Analysis

The program is to be used on a personal computer analyzing patient data in the hospital environment under supervision of a trained physician. The analyzed data can be viewed on the computer screen or printed out on a separate paper.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Micael Hamberg
Medtronic Synectics
Synectics Medical AB
Renstiernas gata 12
S-116 28 Stockholm
Sweden

Re: K972439
Anorectal Manometry Analysis Module
Dated: June 26, 1997
Received: June 30, 1997
Regulatory Class: II
21 CFR 876.1725/Procode: 78 FFX

SEP 23 1997

Dear Mr. Hamberg:

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

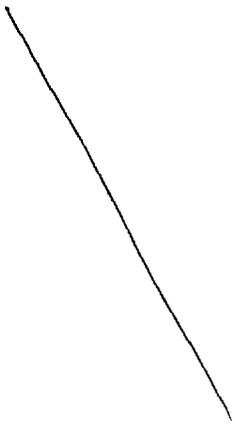
Enclosure

510(k) Number (if known): K972439

Device Name: Anorectal Manometry Analysis Module

Indications For Use:

The Anorectal Analysis Module is a software program that has been designed to analyse pressure data recorded from the lower gastrointestinal tract in pediatric and adult populations.



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

Concurrence of CDRII, Office of Device Evaluation (ONE)

Prescription Use
(Optional Format 1-2-96)

OR

Over-The-Counter Use (Per 21 CFR 801.109)

John A. Rathin
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972439