K961346

9. SMDA 510(k) Summary or Statement

DRAERD 510(k)
Summary of Safety and Effectiveness Information

Submitter's name

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Name of device

pH Analysis Module

Name of equivalent device

EsopHogram Software (DOS environment)
(included in K859361 - Synectics pH System Comprising
Digitrapper Mark II, EsopHogram Software & Monocrystant
Catheter)

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 min and max values, length of selection.

By adding the pH Analysis Module to the Polygram Software for Windows, the user can also have all the intragastroesophageal pH data analyzed (data recorded from the gastrointestinal tract in pediatric and adult population). The analysis report includes sections such as patient demographics; interpretation and comment (for user to insert); procedure summary; pH tracing; period table including number such as duration of recording, number of periods of interest, time where pH was below certain threshold value, symptom correlation, scoring; physician signature section.

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

Statement of intended use/indication for use

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

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.