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## 9. SMDA 510(k) Summary or Statement

*DRAERD 510(k)*  
*Summary of Safety and Effectiveness Information*

### **Esophageal Manometry Analysis Module**

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 are minimum value, maximum value, and the length of the selection.

By adding the Esophageal Manometry 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 Esophageal Manometry Analysis Module has been designed to analyze intragastroesophageal pressure data throughout the gastrointestinal tract.

The Esophageal Manometry Analysis Module has been designed for the same intended use (analyze intragastroesophageal pH data) in both pediatric and adult populations. The product is to be used on patients in the hospital environment under supervision of a trained physician.

Sincerely  
Synectics Medical