



Food and Drug Administration
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April 28, 2016

Given Imaging, Ltd.
Hilla Debby
Director, Clinical & Regulatory
2 Hacarmel St. New Industrial Park POB 258
Yoqneam, 20962
Israel

Re: K151086
Trade/Device Name: ManoScan® System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: FFX
Dated: April 6, 2015
Received: April 8, 2015

Dear Hilla Debby,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151086

Device Name

ManoScan® System

Indications for Use (Describe)

The ManoScan System provides mapping of pressures and, optionally, impedance within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, Sphincter of Oddi, small bowel, colon, duodenum and anorectal organs. It is used in a medical clinical setting to acquire pressures and then store the corresponding data for visualization and analysis. The real-time data as well as the analysis information can be viewed by medically trained personnel for diagnostic and analytic purposes. The ManoScan HRM modules provide high-resolution mapping of the pressure and impedance data. The ManoScan CLT module provides conventional line trace mapping of the pressure data.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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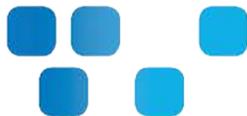
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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: April 21, 2016

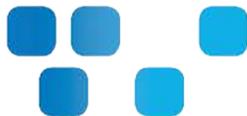
II. DEVICE

Device Trade Name(s): ManoScan® System

Device Common Name: Gastrointestinal motility monitoring system

Classification: Regulation No: 876.1725, Class: II

Panel: Gastroenterology/Urology
FFX – System, Gastrointestinal Motility (Electrical)



III. PREDICATE DEVICE(S)

- ManoScan Motility with Impedance Visualization System (K091070) – Primary Predicate
- Polygram 98 Anorectal Function Testing Application, Polygram 98 Esophageal Manometry Application, Polygraf ID (K011472) – Secondary Predicate

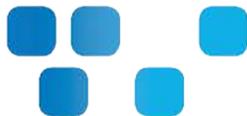
IV. DEVICE DESCRIPTION:

The ManoScan System provides hardware and software for performing gastrointestinal (GI), sphincter of Oddi, and colorectal manometry.

The ManoScan System comprises two sub-systems: the ManoScan HRM System and the ManoScan CLT System. The ManoScan HRM modular series is a high resolution manometry system used for GI manometry. The base system includes a manometric catheter probe, a ManoScan HRM module (A120 module), and software for data acquisition and analysis. Various probe configurations are available depending on the application (esophageal or anorectal manometry), size (regular or small), and catheter diameter. The ManoScan A200 module enables measuring pressure and impedance data using different dedicated catheters. The ManoScan A300 module is used for high-definition 3D catheters which pass pressure data through to the ManoScan A120 module. When enabled, the optional ManoScan A400 module will enable video acquisition through video inputs that originate in typical medical imaging equipment. The ManoScan 3.0 software supports display of video from the ManoScan A400 module (or other video input) and displays it concurrently with pressure (and impedance if enabled) to allow for improved physiological review of the esophageal or anorectal motility function.

The ManoScan CLT series is a conventional line trace system used for GI manometry. The system includes a manometric catheter probe, the ManoScan CLT module (A550), and software for data acquisition and analysis. The system is supplied as an integrated cart system consisting of:

- a cart
- manometric catheter
- ManoScan CLT A550 module



- Computer, monitor and computer peripherals (keyboard, mouse, etc.)
- power isolation station
- ManoScan 3.0 and ManoView CLT software

The ManoScan CLT A550 module acquires pressure data from three catheter types: water-perfused, solid state, and air-charged, manufactured by specific vendors. Each catheter type is connected to the ManoScan CLT A550 module by means of corresponding transducer cable.

V. INDICATIONS FOR USE:

The ManoScan System provides mapping of pressures and, optionally, impedance within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of Oddi, small bowel, colon, duodenum and anorectal organs. It is used in a medical clinical setting to acquire pressures and then store the corresponding data for visualization and analysis. The real-time data as well as the analysis information can be viewed by medically trained personnel for diagnostic and analytic purposes. The ManoScan HRM modules provide high-resolution mapping of the pressure and impedance data. The ManoScan CLT module provides conventional line trace mapping of the pressure data.

VI. TECHNOLOGICAL CHARACTERISTICS:

A comparison of the technological characteristics of the device and predicate devices is presented below in tables 1 and 2:

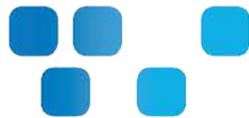
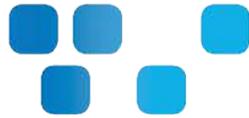


Table 1 – ManoScan System specifications in comparison to Polygraf ID System and ManoScan System:

	Device	Primary Predicate	Secondary Predicate
Device Name	ManoScan System	ManoScan Motility with Impedance Visualization System	Polygram 98 Anorectal Function Testing Application, Polygram 98 Esophageal Manometry Application, Polygraf ID
System Components	HRM modules (A120, A200, A300, A400) CLT Module (A550) Catheters (HRM, impedance, 3D and SUM) Software	HRM modules (A120, A200, A400) Catheters (HRM and impedance) Software	Polygraf ID Module Polygram 98 software SUM catheters
Catheter type	<u>CLT:</u> Water-perfused catheters Solid-state catheter Air-charged catheter <u>HRM:</u> HRM catheter Impedance catheter 3D catheter	HRM catheter Impedance catheter	Water-perfused catheters Solid-state catheter Air-charged catheter
Signals collected	Pressure and Impedance	Pressure and Impedance	Pressure, pH, EMG, respiration and swallow
Recording control	Real time monitoring of signals	Real time monitoring of signals	Real time monitoring of signals
Channels	<u>CLT:</u> 1-16	<u>CLT:</u> NA	<u>CLT:</u> 4-16
	<u>HRM:</u> Number of pressure sensors: 8-256 Number of impedance sensors: 19 (18 channels)	<u>HRM:</u> Number of pressure sensors: 8-36	<u>HRM:</u> NA
Dimensions	<u>CLT:</u> (A550):	<u>CLT:</u> NA	<u>CLT:</u> (A500):

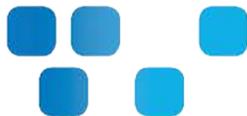


	Device	Primary Predicate	Secondary Predicate
Device Name	ManoScan System	ManoScan Motility with Impedance Visualization System	Polygram 98 Anorectal Function Testing Application, Polygram 98 Esophageal Manometry Application, Polygraf ID
	Width: 331 mm Depth: 245.5 mm Height: 98.5 mm Weight 3.4 kg		Width: 370 mm Depth: 225 mm Height: 73mm Weight: 3 Kg
	<u>HRM:</u> (A120, A200, A300, A400): Width: 341 mm Depth: 245.5 mm Height: 54.5 - 98.5 mm Weight 2.1 – 4.0 kg	<u>HRM:</u> (A120, A200, A400): Width: 331 mm Depth: 245.5 mm Height: 54.5 - 98.5 mm Weight 2.1 – 4.0 kg	<u>HRM:</u> NA
Degree of Protection	Safety Class 1	Safety Class 1	Safety Class 1
Input	110-230 VAC ~ 50/60 Hz	110-230 VAC ~ 50/60 Hz	110-230 VAC ~ 50/60 Hz



Table 2: Description of software features in comparison to predicate devices:

	Device	Primary Predicate	Secondary Predicate
	ManoScan System	ManoScan Motility with Impedance Visualization System	Polygram 98 Anorectal Function Testing Application, Polygram 98 Esophageal Manometry Application, Polygraf ID
510(k) Number		K091070	K011472
Operating system compatibility	Microsoft Windows 7, Windows 8/8.1	Windows XP Professional Service Pack 2	Microsoft Windows 98, Windows 2000 and Windows XP
SW licensing	Yes	No	Yes
pH, EMG, respiration, swallow and EGG applications supported	No	No	Yes
Multi language support	Yes	Yes	Yes
Guide wizard	Yes	Yes	No
Clinical modality/procedure selection	Yes	Yes	Yes
Patient information set up	Yes	Yes	Yes
Calibration	2 point linear calibration for CLT, multiple point calibration for HRM. Monitoring of calibration result for range and resolution requirement.	Multiple point calibration for HRM. Monitoring of calibration result for range and resolution requirement	2 point linear calibration. Monitoring of calibration result for range and resolution requirement
Acquire circumferential data from 3D probe	Yes	No	No
Support visualizations for 3D data	Yes	No	No



The main mechanical differences in the ManoScan CLT A550 module are in comparison to the Polygraf ID module and new software versions to support line trace manometry applications. However, it may be concluded from the Substantial Equivalence Summary that none of the presented changes raise any new safety issues.

Both the subject and predicate devices have the same intended use for mapping pressure levels within the tubular organs of the GI tract. The predicate device, ManoScan System for high resolution manometry, also has an additional use of recording impedance data.

VII. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and Electromagnetic compatibility (EMC) testing were conducted on the ManoScan System, consisting of the modules and supported catheters, the system complies with IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Bench Testing – Hardware Verification

A Hardware verification test was performed to evaluate the performance of the ManoScan CLT A550 module hardware and embedded software.

Bench Testing – Pressure Mapping

Pressure mapping test was conducted to verify that the mapping of pressure data of ManoScan CLT A550 module is equivalent to that of the predicate device, Polygraf ID module.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices." The software for this device is considered as a "moderate" level of concern, since a malfunction or a latent design flaw in the Software could lead to an erroneous diagnosis or a delay in delivery of appropriate



medical care that would likely lead to Minor Injury.

The proposed changes in this submission do not raise new performance or safety issues.

VIII. CONCLUSION:

Based on the technological characteristics of the devices, Given Imaging Ltd. believes that the ManoScan System and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.