SEP 28 2012

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.92)

Submitter Details

PeerMedical Ltd.
2 Hatochen St., PO 3161
Business and Industrial Park (North), Caesarea, 38900, Israel
Tel: +972 4 6327731, Fax: +972 4 6327734
Date summary prepared: June 2012
Submission Contact: Dan Laor, 6 Sireni St., Haifa, 32972, Israel.

Device Details

Proprietary Name:	PeerScope System
Common Name:	Colonoscope and accessories, flexible / rigid
Classification Name	Endoscope accessories, 21 CFR 876.1500
Product Code:	FDF
Subsequent Product Code:	KOG
Committee/Panel:	Gastroenterology/Urology
Device Class:	II

Reason for 510(k) Submission: New Device

Identification of Legally Marketed Predicate Devices
ProtectiScope CS –K081004 - Manufactured by Stryker GI

Device Description
The PeerScope system consists of endoscopic Main Control Unit (MCU), and of the PeerScope CS colonoscope. The MCU controls the endoscope. As other endoscopic legally marketed systems, it includes video system, light source, and interface to other ancillary equipment. The device labeled for use in healthcare facility/hospital for endoscopy and endoscopic treatment within the lower digestive tract. The operation principles of the PeerScope System are similar to those of other legally marketed standard colonoscopy systems. The PeerScope system model provides 160° standard front field of view and a 300° wide field of view.

Intended use and indications for Use
The PeerScope System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The PeerScope System is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients. The PeerScope System consists of PeerMedical camera heads, endoscopes, video system, light source and other ancillary equipment.

Technological characteristics

The technological characteristics of PeerScope system were compared to the characteristics of the predicate device and were found very similar, in terms of: endoscope geometry, illumination type, energy source, lens irrigation, air flow and air pressure. Several differences were observed and are listed below:

Category	ProtectiScope CS K081004	PeerScope System	Impact of the differences on device performance
Brightness Control	Automatic or Manual	Factory Adjusted	Factory Adjusted method provides reliable design without compromising performance.
Output Video signals	VBS 2 channels Y/C 2 channels DVI 2 channels	Composite 3 channels Y/C 3 channels	Both devices utilized industry accepted standard Output Video signals.
Foot Switch	Included	Not Included	The foot switch is used to operate the ProtectiScope CS unique feature which is not included in the PeerScope System specifications.
Water Flow rate for Auxiliary Jet water supply	20 cc/sec	4.0 cc/sec	The design of the reduced jet water flow has been verified & validated. The results demonstrated that the jet irrigation is efficient.
Disposable Sleeve	Included	Not Included	The disposable sleeve is a unique feature which is not included in the PeerScope System specifications.

Based on the results of verification, validation and performance testing, the impact of the above differences is insignificant in terms of the device safety and effectiveness for its intended use.

Performance data

Bench data:

The device safety and performance were verified by tests by PeerMedical and accredited third party laboratories. List of standards was used / relied upon for testing:

IEC 60601-1: 1988 + Am. #1 (1991), #2 (1995)
IEC 60601-2-18:1996 /EN 60601-2-18:1996 2nd Ed. +Am.1 (2000)
IEC 60601-1-2:2007
ISO 10993:2009 Part #1
ISO 10993:2009 Part #5
ISO 10993:2010 Part #10
ISO 10993:2007 Part #12
ISO 8600-4 First edition 1997-07-01
ISO 8600-1 Second edition 2005-05-01
ISO 8600-3 First edition 1997-07-01 Am 1
ISO 8600-6 First edition 2005-03-15
ASTM E 1837- 96 (reapproved 2007)

Reprocessing validation was carried out in accordance with " Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Draft Guidance / May 2011.

The device performance was validated by testing of a final production unit in simulated clinical conditions focusing on evaluation of the device wide 300° field of view. The procedure was performed by physicians at three US medical centers. Methods and procedures were identical to those used in clinical conditions. The results of the bench validation passed the experiment criteria. The device met its intended use and specifications. Hazardous conditions were not observed.

Clinical Data:
The device performance was validated by testing of a final production unit in clinical conditions. The procedure was performed at Elisha Medical Center, Haifa, Israel on a diverse adult population in terms of gender, ethnicity and age. The procedure was performed by US, European and Israeli physicians. Methods and procedures were identical to those used in US-based studies. Fifty (50) patients were enrolled in conformance with the device labeling. The results of the clinical validation passed the experiment criteria. No adverse events were observed.

The conclusions drawn from the bench and clinical tests demonstrate that the device meets its specifications, intended use and indication for use.

Substantial Equivalence

The above presented data demonstrate that:

a. The predicate device ProtectiScope CS –K081004 is legally marketed.
b. The PeerScope System and the predicate device have the same intended use.
c. The PeerScope System does not raise different questions of safety and effectiveness.
d. The data provided demonstrate equivalence and support the indications.

Conclusion: It is the opinion of PeerMedical that the PeerScope system is substantially equivalent to the predicate device, in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PeerMedical Ltd.
% Mr. Dan Laor
Quality & Regulatory Advisory
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HAIFA 32972
ISRAEL

SEP 28 2012

Re: K120289
Trade/Device Name: PeerScope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: August 14, 2012
Received: August 15, 2012

Dear Mr. Laor:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, 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): K120289

Device Name: PeerScope System

Indications For Use:
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120289