510(k) Summary for K130165

Submitter:	Advanced Planimetric Services, LLC
Address:	610 Boulevard, Elmwood Park, New Jersey 07407
Telephone:	646-220-1745
Contact Person:	Dr. Martin Wendelken
Date of Summary:	28- August- 2013
Trade Name:	PictZar®
Common Name:	Wound measurement and documentation software
Classification Name:	Surgical camera and accessories (21CFR878.4160)
Class :	Class I (general controls)
Predicate Devices:	Verg Videometer (Verg Incorporated) Visitrak (Smith & Nephew) Silhouette (Aranz Medical Ltd.)
Device Description:	PictZar® is digital planimetry software used for the measurement and tracking
Indications for Use:	PictZar is indicated for wound measurement and documentation and can be used on all external wound types.
Intended Use:	The intended use of PictZar® planimetry software is to measure and document the progression of external wounds over time. This system is a computer software application. The system is a non-contact method of wound measurement.
Comparison to Predicates:	PictZar® is substantially equivalent to the predicate devices in the comparison of the indications for use, the intended use, how it is used relating to workflow using current principals and technology. Measurements made PictZar® are equal to or more accuate than those made with the predicate devices. The differences do not raise any questions of safety and effectiveness over the predicate devices.

AUG 3 0 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 30, 2013

Advanced Planimetric Services, LLC
Dr. Martin E. Wendelken
President
610 Boulevard
Elmwood Park, New Jersey 07407

Re: K130165
Trade/Device Name: PictZar[90] Digital Planimetry Software Application
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical camera and accessories
Regulatory Class: Class I
Product Code: FXN
Dated: May 27, 2013
Received: June 05, 2013

Dear Dr. Wendelken:

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,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K130165

Device Name: PictZar® Digital Planimetry Software and Documentation System

Indications For Use:

PictZar® planimetry software is indicated for wound measurement and documentation and can be used on all external wound types.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Neil R Ogden
2013.08.30 12:49:15 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130165