K070426

510(k) Summary of Safety and Effectiveness

JUN 29 2007

Submitter:	ARANZ Medical Limited
Address:	Ground Floor, St Elmo Courts 47 Hereford Street, PO Box 3894 Christchurch 8013
Phone:	+64 3 3746120 ext 217
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Contact:	Shane Goodwin
Trade name:	Silhouette
Common name:	Wound measurement and documentation system
Classification name:	Surgical camera and accessories (21 CFR 878.4160)
Class:	Class I (general controls)
Predicate Devices:	Verge Videometer (Verg Incorportated) Visitrak (Smith & Nephew)
Device Description:	Silhouette consists of a camera connected to a PDA, for the measurement and tracking of wounds
Indications for Use:	Silhouette is indicated for wound measurement and documentation and can be used on all external wound types.
Intended Use:	The intended use of the Silhouette system is to measure and document the progression of external wounds over time. The Silhouette system is comprised of a camera (SilhouetteCamera) connected to a PDA running a software application (SilhouetteMobile Software) to capture and document images taken by the user. A software accessory (SilhouetteServer) on a PC may be used to transfer images and documentation to a third-party patient information database. The system is non-contact with respect to the patient.
Comparison to Predicates:	Silhouette is substantially equivalent the predicate devices, considered in light of the comparison of the indications for use, the intended use, the workflow of the devices and the technological principles being applied. Standard wound measurements made with Silhouette are more accurate than those made with the predicate devices. These differences do not raise questions safety and effectiveness over the predicate devices.
Date of Summary:	17 January 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Aranz Medical Limited
% Shane Goodwin
Regulatory Scientist
St. Elmo Courts
Ground Floor
47 Hereford Street
P.O. Box 3894
Christchurch, New Zealand

Re: K070426
Trade/Device Name: Silhouette Wound Measurement and Documentation System
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical camera and accessories
Regulatory Class: I
Product Code: FXN
Dated: June 18, 2007
Received: June 20, 2007

Dear Shane Goodwin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070426

Device Name: Silhouette Wound Measurement and Documentation System

Indications For Use:

Silhouette is indicated for wound measurement and documentation and can be used on all external wound types.

Prescription Use ___✓___ 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 General, Restorative, and Neurological Devices

510(k) Number K 070426