510(k) Summary

AUG 2 2 2012

Summary of 510(k) Safety and Effectiveness

Submitted By:	Alliance Partners, LLC 121 Interpark Blvd, #601 San Antonio, TX 78216
Date:	August 13, 2012
Contact Person:	Jennifer Palinchik Regulatory Consultant
Contact Telephone:	(440) 933-8850
Device Trade Name:	SwannShidi Bone Marrow Aspiration Needle
Device Classification Name:	Gastroenterology-urology biopsy instrument
Device Classification:	Class II
Reviewing Panel:	Gastroenterology/Urology
Regulation Number:	876.1075
Product Code:	KNW
Predicate Device:	Busse Hospital Disposables I-Style Bone Marrow Aspiration Needle (K061570) H.S. Hospital Service S.p.A. BMN "I" Type Marrow Biopsy Needle (K020987) Ranfac Corporation Goldenberg SNARECOIL Needle (K031344)

Device Description:

The SwannShidi Bone Marrow Aspiration Needle consists of a 15ga needle and an angled tip stylet of corresponding size. A depth gauge with graduated scale and additional locking mechanism allows for adjustment of the penetration section of the needle. A luer lock connection is provided to allow aspiration of bone marrow or autologous blood by use of a standard surgical syringe. The SwannShidi is a single use, disposable device that will be supplied sterile.

Intended Use:

The SwannShidi Bone Marrow Aspiration Needle is to be used for aspiration of bone marrow or autologous blood by use of a standard syringe.

Substantial Equivalence Information:

The design features, principles of operation, materials, indications for use, biocompatibility, and sterilization method of the SwannShidi are substantially equivalent to the predicate devices listed

above. The minor technological differences between the SwannShidi and its predicate devices raise no issues of safety and effectiveness.

Predicate Comparison Summary Table:

Item	**SwannShidi**	**Busse Hospital Disposables I-Style Bone Marrow Aspiration Needle**	**H.S. Hospital Service BMN "I" Type Marrow Biopsy Needle**	**Ranfac Goldenberg SNARECOIL Needle**
Product Code	KNW	KNW	KNW	KNW, FCG
Regulation Name	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument
Intended Use	for aspiration of bone marrow or autologous blood by use of a standard syringe	for aspiration of bone marrow	for drawing of osteomedullary substance or for explanation of bone marrow	for obtaining a percutaneous soft tissue biopsy
Needle Size	15 gauge	Same	Same	11-16 gauge
Stylet	Yes	Yes	Yes	Yes
Angled Tip	Yes	Yes	Yes	Yes
Male luer connection	Yes	Yes	Yes	Yes
Material-Needle/Stylet	Stainless Steel	Same	Same	Same
Material-Plastic Components	Medical Grade Plastic	Same	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same	Same

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

Alliance Partners, LLC
% Ms. Jennifer Palinchik
Regulatory Consultant
121 Interpark Boulevard, # 601
San Antonio, Texas 78216

AUG 2 2 2012

Re: K121181
Trade/Device Name: SwannShidi Bone Marrow Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 13, 2012
Received: August 14, 2012

Dear Ms. Palinchik:

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

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K121181

Device Name: SwannShidi Bone Marrow Aspiration Needle

Indications for Use:

The SwannShidi Bone Marrow Aspiration Needle is to be used for aspiration of bone marrow or autologous blood by use of a standard syringe.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121181