Summary of Safety and Effectiveness

Sterylab S.r.l.
Via Magenta 77/6
Rho (MI), Italy 20017

Non-Confidential Summary of Safety and Effectiveness

3-Jul-05

Official Contact:	R. Zambelli – President
Proprietary or Trade Name:	Bone Biopsy – Ben, Best Liasa, Mielo-Can Soft Tissue Biopsy - Spring-Cut, Bio-Cut, Fast-Gun, Colt
Common/Usual Name:	Biopsy needle and needle set, gastro-urology Biopsy instrument
Classification Name:	FCG - Biopsy needle and needle set, gastro-urology KNW – Biopsy instrument
Predicate Devices:	MD Tech K980196 – Manan Biopsy Set for Bone and Bone Marrow K974814 – Manan Super Core Biopsy K990839 – Tru-Core 1 Reusable biopsy instrument K980226 – Manan Pro-Mag Automatic Biopsy system

Device Description

The Sterylab family of biopsy products which include diffenet needles and handles for various procedures. The configurations include manual, semi-automatic and automatic systems. They incorpate various needles styles fto optimize capture of the biopsy samplea nd minize patient discomfort. The soft tissue devices use guillotine-type needles and consist of a a spring-powered system. Each can regulate the depth of the tinsertion. Some may be used in MRI environments.

Indications for use

Bone and Bone marrow biopsy devices – Ben, Best Lisas, and Mielo-Can are indicated to harvest bone and / or bone marrow specimens. The pediatric bone marrow needle is intended for the purpose of obtaining access to the medullary cavities for the purpose of initiating resuscitative infusion or for aspirating marrow in pediatric patients.

Soft Tissue Devices – Spring-Cut, Bio-Cut, Fast-Gun and Colt are indicated to provide tissue samples of various soft organs and tissues, including, but not limited to, biopsies for breast, lung, thyroid, liver, pancreas, spleen, kidneys, and prostate, for diagnostic sampling of abnormalities. They are designed to provide tissue for histological examination with partial or complete removal of the imaged abnormality.

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Indications for use (continued)

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Environment of Use

Hospital, Sub-acute Institutions, Physician office, Outpatient settings, and in some cases MRI environments.

General Technical Characteristics

Characteristics	Bone / Bone Marrow Ben, Best Liasa, Mielo-Can	Soft Tissue Spring-Cut, Bio-Cut	Soft Tissue Fast-Gun, Colt
Indications for use	Bone marrow biopsy	Various soft organs and tissues, including, but not limited to, biopsies for breast, lung, thyroid, liver, pancreas, spleen, kidneys, and prostate	
Needle, cannula	Single lumen needle with internal style that is advanced manually	Single action needle. Single lumen needle with internal stylet with guillotine-type needle	Dual action needle. Single lumen needle with internal stylet with guillotine-type needle
Available sizes needles, cannulas	Needle / Cannula – 7 -18 gauge	Needle / Cannula – 14 - 20 gauge	Needle / Cannula – 14 - 20 gauge
Needle advancement / penetration depth	Length of needle – 9 cm to 15 cm Depth controlled by user by setting the stopper	Length of needle – 90 mm to 470 mm Depth / throw 6, 12, 20 mm pre-set	Length of needle – 90 mm to 470 mm Depth / throw 6, 12, 20 mm pre-set
Sample notch size	20 mm	20 mm	20 mm
Number of samples	One sample Mielo – 2 samples	One sample	One sample
Mechanics of action	Manual Spring operated	Manual Spring operated	Manual Spring operated
Mode of action Single puncture / sample	Single puncture and sample	Single puncture and sample	Single puncture and sample
MRI compatibility	No	Yes	Yes
Materials in patient contact	SS AIS 304 SS AIS 302	SS AIS 304 SS AIS 302 Titanium grade 2	SS AIS 304 SS AIS 302 Titanium grade 2

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed devices and the predicates and raise no new safety or effeciaicy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Sterylab S.R.L.
c/o Mr. Paul E. Dryden
Regulatory Consultant for Sterylab S.r.l.
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K051506
Trade/Device Name: Sterylab Biopsy devices
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG, KNW
Dated: June 04, 2005
Received: June 7, 2005

Dear Mr. Dryden:

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.

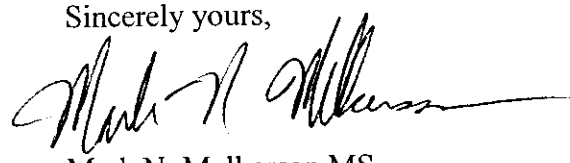
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson,MS
Acting 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): K051506

Device Name: Sterylab Biopsy devices

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Prescription Use **XX** 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)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051506