MAY 2 3 2003

K031344

510(k) Summary
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Submitter's Name and Address:	Ran*fac* Corporation 30 Doherty Avenue Avon, MA 02322-0635
Manufacturer's Contact Person:	Barry Zimble Executive Vice President Tel: (508) 588-4400 Fax: (508) 584-8588
Date Summary Prepared:	April 21, 2003
Device Trade Name:	**Goldenberg SNARECOIL™ Soft Tissue Biopsy (GSS) Needle**
Common name: **Classification Name:**	Biopsy Needle Biopsy Instrument (21 CFR 876.1075) Product Codes: KNW, FCG
Predicate Device(s):	Ranfac Single Action Biopsy Needle Ranfac Goldenberg Bone Marrow Biopsy Needle Ethicon Endo-Surgery Inc. Mammotome Hand Held 11 Gauge Biopsy Probe
Device Description:	The subject device is a sterile disposable product featuring a stationary stylet that punctures, a spring-activated cannula that cuts and a SNARECOIL that captures tissue. The device functions by pulling back the pull ring until the trigger cocks and pressing the trigger until the device fires. The biopsy is captured by the snare located inside the outer needle cannula.
Intended Use:	The Goldenberg SNARECOIL™ Soft Tissue Biopsy (GSS) Needle is intended for obtaining a percutaneous soft tissue biopsy.

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Technological Characteristics:	The proposed device has similar technological characteristics and is similar in design and configuration compared with the predicate devices.
Non-Clinical Data:	Performance verification testing demonstrated that the SNARECOIL Soft Tissue Biopsy (GSS) Needle is functionally acceptable.
Clinical Data:	Not Applicable
Conclusion:	Based on similarities in materials, design, operating principles, biocompatibility and sterilization method between the GSS Biopsy Needle subject of this premarket notification and the predicate devices, the GSS Biopsy Needle has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Mr. Barry Zimble
Executive Vice President
Ranfac Corporation
30 Doherty Avenue
Avon, Massachusetts 02322-0635

Re: K031344
Trade/Device Name: Goldenberg Snarecoil™ Soft Tissue Biopsy (GSS) Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: April 23, 2003
Received: May 1, 2003

Dear Mr. Zimble:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031344

Device Name: **Ran*fac* Goldenberg SNARECOIL™ Soft Tissue Biopsy (GSS) Needle**

The GSS Biopsy Needle is intended for obtaining a percutaneous soft tissue biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

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Prescription Use X OR Over-the -Counter Use ___
(Per 21 CFR 801.109)