DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Ranfac Corporation
c/o Ms. Annette M. Fagnant
Boston Biomedical Associates
53 Kennedy Road
Foster, Rhode Island 02825

Re: K032478
Trade Name: Disposable Suture Grasper Needle
Classification Regulation Name and Number: Gynecologic Laparoscope and Accessories, 21 CFR 884.1720
Regulatory Class: Class I Exempt
Product Code: KOG
Dated: August 8, 2003
Received: August 12, 2003

Dear Ms. Fagnant:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 884.9. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 884.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Mr. Anthony D. Watson at (301) 594-3090 or the Division of Small Manufacturers, International and Consumer Assistance at its

toll free number (800) 638-2041 or (301) 442-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milkerson

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