DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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FEDERAL EXPRESS

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Merril T. Dayton, M.D.
University of Utah
School of Medicine
50 North Medical Drive
Salt Lake City, Utah 84132

Dear Dr. Dayton:

During August 5-30, 1996, you were inspected by T. M. Steinke, an investigator with the Food and Drug Administration's (FDA) Denver District Office. The purpose of that inspection was to determine whether your activities and procedures as principal investigator of an investigational study of the complied with applicable regulations. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our review of the inspection report submitted by the District Office revealed violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions. These items were presented to you as observations on form FDA-483 by Investigator Steinke and discussed with you at the conclusion of the inspection on August 30, 1996. The following list of violations is not intended to be an all-inclusive list of deficiencies in the above referenced clinical study:

1. **Failure to conduct an investigation in accordance with the investigational plan and conditions of approval of the IRB as required by 21 CFR 812.110(b).**

   The study protocol requires that the subject be evaluated during a follow-up surgery by an adhesion evaluator blinded to the subject's randomization assignment of the initial surgery. The study's "Investigator's Statement," which you signed on May 11, 1993, . as the adhesion evaluator at your clinical site.

   Study records indicate that only 4 of 37 subjects' follow-up surgery adhesion evaluations were performed by Furthermore, the inspection disclosed that the balance of these adhesion evaluations, 33 out of 37, were not done by a blinded evaluator.

   In addition, two subjects enrolled in the study, did not meet the protocol inclusion/ exclusion criteria.

2. **Failure to submit reports of unanticipated adverse device effects to the reviewing Institutional Review Board (IRB) and Sponsor no later than 10 days after occurrence as required by 21 CFR 812.150 (a)(1).**

   Adverse events which involved subjects and were not reported to the sponsor or the IRB. Additionally, reports to the sponsor and IRB were delayed significantly for a serious adverse event involving subjects

3. **Failure to ensure that proper informed consent is obtained as required 21 CFR 812.100.**

   The Informed Consent Documents (ICDs) did not meet the requirements of 21 CFR 50.25 in that ICD did not include information which the sponsor directed to be amended per letter dated April 22, 1993.

   The consent obtained was inadequate in that there was no documentation of consent as required by 21 CFR 50.27 for subjects

4. **Failure to keep accurate records of the receipt, use or disposition of the investigational device as required by 21 CFR 812.140 (a)(2).**

   Randomization forms, which show whether or not a patient received the investigational device and how many, were not complete and accurate for subjects ,

These above violations are not intended to be an all-inclusive list of violations in your clinical study. It is your responsibility to ensure adherence to all requirements of the Act relevant to device clinical investigation or research.

We have also completed our review of your December 10, 1996, response to the FDA-483. This response will be placed in the permanent record. You acknowledged the seriousness of the violations and promise that efforts will be made to avoid recurrence. The adequacy of your corrections may be verified in a future inspection.

A copy of this Warning Letter has been sent to the Food and Drug Administration, Denver District Office, P.O. Box 25087, Denver, CO 80225. Any further correspondence should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch-I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: L. Glenn Massimilla, R.Ph. We request that a copy of any correspondence also be sent to the Denver District Office.

Please direct all questions concerning this matter to Mr. Massimilla at 301-594-4720, ext. 136.

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health