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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER
VIA FEDERAL EXPRESS

JUL 14 1999

Mr. James L. Richey
General Manager, Ireland & Vice President, Waltham
Summit Technology Ireland B.V.
Cork Business & Technology Park, Model Farm Road
Cork, Ireland

Dear Mr. Richey:

During an inspection of your facility located in Cork, Ireland, on May 4/7, 1999, our investigator determined that your firm distributes Summit Krumeich-Barraquer microkeratomers and their accessories and components. This includes distribution of sterile disposable stainless steel blades that are used in the microkeratome. The microkeratome and its components/accessories are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act) and are subject to the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation found in Title 21 of the Code of Federal Regulations (CFR) Part 820.

This current inspection disclosed that your firm has the microkeratomers and their components/accessories manufactured for you by [REDACTED], either in [REDACTED], [REDACTED] or in Cork, Ireland. Your firm is doing all of the finished device testing and the finished devices are distributed under your firm's name indicating your firm as the manufacturer. The inspection of your facility revealed that the microkeratome blades are adulterated because the Master Record for the Summit Krumeich-Barraquer Microkeratome fails to contain sterilization specifications for the cutting blade that is labeled as sterile. Also, no documentation was made available to show that the packaging for the sterile cutting blade had ever been tested for integrity. This is a violation 21 CFR 820.181, failure of the Device Master Record to contain production process specifications and packaging specifications.

Your response to the FD483 confirmed that no sterilization specifications for the microkeratome blades were available during the inspection at Cork. You indicated that specifications and validation of the packaging integrity were available at [REDACTED] (written in [REDACTED]). Individuals at your facility in Cork were unable to answer questions regarding the sterility of these blades and the packaging integrity, yet were responsible for the finished device testing. Your response also indicated that you have implemented a plan to require the cutting blade package to conform to ISO 11737, "Sterilization of Medical devices: Microbiological Methods, Part I: Estimation of the Population of Microorganisms in Products and Part II: Tests of Sterility Found in the Validation of a Sterilization Process." This plan should support a minimum sterilization cycle that provides a Sterility assurance Level of 10 to the minus 6.

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This response, as well as the lack of documentation supplied to FDA to demonstrate the adequacy of the [REDACTED] sterility specifications and package integrity validation raises concerns as to whether the microkeratome blades distributed by your firm were adequately sterilized. You have indicated that a report documenting your new sterilization and package integrity validation is due to be issued by July 31, 1999. If you cannot demonstrate that the devices sterilized by the previous procedures were adequately sterilized and had the integrity of the packaging adequately validated, please indicate what your plans are regarding these devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonable related will be cleared until the violations have been corrected

Given the serious nature of these violations of the Act, all microkeratome blades manufactured by [REDACTED] or Summit and distributed by Summit for use with the Krumeich-Barraquer Microkeratome may be detained upon entry into the United States until these violations are corrected. You need to provide FDA with documentation showing that these microkeratome blades were adequately sterilized and that the package integrity was validated as soon as possible.

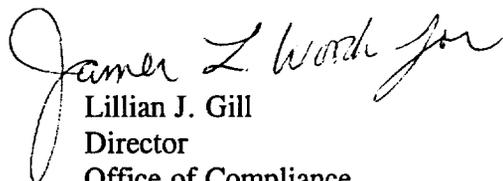
In order to remove these devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified your products may resume entry into this country.

Please notify this office in writing within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

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Your response should be sent to the attention of Ms. Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch, at the letterhead address.

Sincerely yours,

A handwritten signature in cursive script that reads "Lillian J. Gill". The signature is written in black ink and is positioned above the printed name and title.

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