ExSull, Inc.
319 Lombardy Road
Drexel Hill, PA 19026
SEK 4/9 & 6/25-27 (97)

SUMMARY OF FINDINGS:

Inspection of a Medical Device manufacturer of excimer lasers, ExSull, Inc., 319 Lombardy Road, Drexel Hill, PA 19026, was conduct as per request from CDRH/OC, to ascertain the firm's current activities regarding the manufacture of excimer lasers for use in ophthalmological (LASIK) surgery. The inspection was conducted according to PHI-DO Assignment #97-0147 and CPGM 73820.830L. Joseph L. Despins, CSO, accompanied me on 4/9/97, but was not present during the any of the other inspectional dates. I (Steven E. Kane, CSO) have written the entire EIR, and Investigator Despins has checked the accuracy of the EIR, for only those parts of the EIR that relate to the 4/9/97 inspectional date (including parts stating "we" or "us").

Previous inspection, 5/16/96, was a follow up to a Warning Letter issued on 8/17/95. The Warning Letter informed the firm that the FDA considered ExSull, Inc., to be a manufacturer of a Class III medical device, that was both adulterated and misbranded, in that there were no approved PMA or IDE for any of the devices and that the firm itself was not registered as a medical device manufacturer. The inspection determined that the firm continued to service the excimer laser devices for their previous customers, but had not contracted with any new customers, since the receipt of the Warning Letter. An FDA-483 was issued and the inspection was classified [redacted]

The current inspection revealed that the firm is responsible for the overall design specifications and assembly for each excimer laser, and that the firm has also developed the software program, that controls the "beam shaping" or "sculpting" mechanism (also developed by the firm). The inspection found significant GMP violations, including: no software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism; failure to maintain Device Master Records or Device History Records; failure to maintain written manufacturing specifications and processing procedures; and failure to maintain complaint files. An FDA-483 was issued regarding these observations.

In addition, the inspection determined the following: that the firm maintains they have not contracted with any physicians since the completion of the last device, in October 1996; the firm continues to provide service for the [redacted] physicians still under contract; that Mr. Sullivan has recently developed specialized software (for at least one client), to treat an [redacted] caused by [redacted] and verified a list of