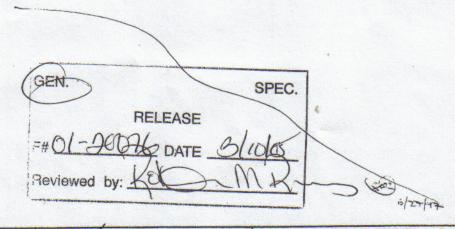
DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	PSHH2/PORESSOD & DRMMADMINISTRATION ARM 900 U.S. Customhouse Second and Chestnut Streets Philadelphia, PA 19106-2973	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED	PERIOD OF INSPECTION	C. F. NUMBER
TO: Edward J. Sullivan	4/9;6/25,26,27	2530807
TITLE OF INDIVIDUAL	TYPE ESTABLISHMENT INSPECTED	
President	Medical Device Manufacturer	
FIRM NAME	NAME OF FIRM, BRANCH OR UNIT INSPECTED	
Exsull, Inc.	Same	
STREET ADDRESS	STREET ADDRESS OF PREMISES INSPECTED	
319 Lombardy Road	Same	
CITY AND STATE (Zip Code)	CITY AND STATE (Zip Code)	
Drexel Hill, PA 19026	Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

- 1. The firm does not have any software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism (sometimes refered to as a "Controllable Iris/Slit with Laser Pulsar", and also designed by the firm), that the firm sold to and installed in approximately ophthalmological Excimer lasers located in Physician's offices, sometime between August 1994 and October 1996.
- 2. The firm does not follow GMP regulations in that:
 - a) The firm does not maintain Device Master Records or Device History Records.
 - b) Does not maintain complaint files.
 - c) Does not maintain written manufacturing specifications and processing procedurs
 - d) Does not have the above documents, readily available, for review and copying by designated employees of FDA, at a location that is reasonably accessible to FDA employees.

The observations noted in this FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the GMP regulation.



SEE REVERSE OF THIS PAGE EMPLOYEERS) SIGNATURES

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Steven E. Kane, Investigator

DATE ISSUED 6/27/97