DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration Rm. 900 US Customhouse, 2nd and Chestnut Sts. Phila. PA 19106 (215) 597-4390	4/19,20, 23-30, 30, 5/1-4,7, 10/2001
	FEI NUMBER 2531320

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Herbert J. Nevyas MD

FIRM NAME	STREET ADDRESS
Medical Director	2 Bala Plaza, 333 City Ave
CITY, STATE AND ZIP CODE Bala Cynwyd PA 19004	TYPE OF ESTABLISHMENT INSPECTED Sponsor/Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemption (Protocol # NEV-97-001) for the indicated study, "LASIK (Laser Intrastromal Keratomileusis) with an Excimer Laser in the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

1. There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.

   For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later

2. The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.

3. There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Ronald Stokes	Ronald Stokes	May 10, 2001