APR 0 6 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

APR - 1 1998

Re: G970088

Dear Dr. Nevyas:

You currently have an investigational device exemption G970088 for your laser. If you should ultimately wish to submit a premarket approval application (PMA) for this laser, please use the following guidance as to the type of information you need to submit to FDA regarding manufacture of your device.

If you do not intend to manufacture additional units of the excimer laser system that is the subject of your PMA, FDA will forego a Good Manufacturing Practices (GMP) inspection, but we will require you to submit manufacturing information in the Manufacturing Section of your PMA. In the past communications with your consultant, Barbara Fant, Pharm.D., we have stated that this information should include:

complete specifications for the laser unit, including operating parameters;

acceptance specifications for raw material and components;

a description of the complaint file procedures; and

procedures for change controls for any changes in the design of the one laser unit.

FDA 0 0037

The above-listed requirements are critical to the submission of your PMA Manufacturing Section, but cannot legally constitute a complete list of the information you will need to submit for this section. Section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that an application for premarket approval for a Class III device, such as yours, shall contain "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and , when relevant, packing and installation of, such device." 21 U.S.C. 360e(c)(1)(C). Similarly, 21 C.F.R. 814.20(b)(4)(v) requires that unless an applicant