b. Those eyes rescheduled from same day to different day surgery should be accounted for.

c. If the exclusion criteria of the original protocol do not specifically mention the exclusion of patients with anterior segment lid diseases (e.g., blepharitis, etc.), then the substudy protocol should specifically exclude patients with these conditions for same day fellow eye surgery.

d. FDA believes that a one day interval is not sufficient to qualify as a "different day" procedure. It is recommended that the protocol for the substudy be altered to have a minimum 2-week waiting period prior to fellow eye treatment.

e. Your statement in the rider to the informed consent document that "...There have been no failures or malfunctions of the Willis Excimer Laser", should be removed or altered. It may unduly influence potential same day fellow eye surgery candidates into believing that the Nevyas Excimer Laser cannot fail. FDA recommends that you remove this statement or alter it to read: "There have been no failures or malfunctions of the Nevyas Excimer Laser to date."

f. Please specify the minimum time between treatment of same day fellow eyes, in patients order to evaluate for complications. 1/2 hr.

g. These same day fellow eye subjects are considered part of your overall total, currently 100 eyes low myopia and 25 eyes high myopia.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850