X. ETHICAL AND REGULATORY CONSIDERATIONS

A. INVESTIGATOR/SPONSOR: In accordance with 21 CFR 812.3(o), Dr. Herbert Nevyas and Dr. Anita Nevyas-Wallace are the "Sponsor-Investigators," for the Nevyas Excimer Laser, meaning they are the individuals who both initiate and actually conduct, alone or with others, an investigation; and that the investigational device is administered, dispensed, or used under his/her immediate direction. The regulatory obligations of a "sponsor-investigator" include those of an investigator as well as those of a sponsor.

B. INFORMED CONSENT: In accordance with the provision of 21 CFR Part 50, each patient will give written informed consent for participation in this study prior to the use of the investigational device. A copy of the basic elements of informed consent is attached (Appendix E). The study will be explained to the prospective patient by the investigator or his designee. The nature of the investigational device will be explained together with potential hazards of the surgical procedure, including any possible adverse reactions. The patient will be informed that he/she is free to terminate participation in the study for any reason. One copy of the consent form will be given to the subject and a copy of the signed consent form will be kept on file by the investigator. A copy of the IRB-approved informed consent form will be retained in the investigator's files prior to initiating the study.

C. INSTITUTIONAL REVIEW BOARD: This protocol, and the informed consent form, will be approved initially and reviewed annually by an Institutional Review Board constituted according to FDA regulations. The Institutional Review Board granting initial approval shall be responsible for continuing review and approval of this study including the informed consent form. A copy of the Committee's dated approval and a list of the members of the Institutional Review Board, or its DHHS approval number, will be given to the investigator for the investigator's files. Progress reports will be submitted at the completion of the study or at least once yearly, whichever comes first, to the Institutional Review Board (IRB). Serious and unanticipated adverse device effects will be reported to the IRB and the FDA.

D. COMPLICATIONS & ADVERSE EVENTS: Complications or adverse events that are observed by the investigator or reported by the subject should be recorded on the data collection sheets or in the computerized database. For all adverse events, a description