[redacted]
10/6,7,8,13,14,15,20
22,23,26,27,30-
11/2/98 RALS

It also serves as an enrollment form for the clinical study. According to [redacted] they always ensure the patient understands the form before proceeding. The patient is then either scheduled for surgery at a later date or it is performed the same day the form is signed.

The emission from the laser passes through a safety shutter, beam shaping optics, beam modulator, imaging optics and finally is reflected downward into the working region. The operation of the laser, shutter and beam shaping optics is controlled by a computer system.

The desired lens correction information is entered into the computer which controls the laser beam size and delivered energy density during the ablation process. First a very thin corneal flap is created using an instrument called a microkeratome (provides suction to eye to flatten it and a blade to cut the cornea). When the eye is properly positioned, the operator uses a foot pedal to activate the laser and ablate the corneal tissue to achieve the desired lens correction. The corneal flap is then repositioned to heal.

The surgical procedure with associated pertinent information is recorded on an Excimer Laser Log/Intra-Operative form **EXHIBIT #18**. A copy of the form is filed in a logbook and another copy is placed in the patients' file.

[redacted] initial IDE submission was disapproved May 8, 1998. He was granted conditional approval on August 7, 1998. As [redacted] addressed various issues presented in letters from FDA CDRH/ODE he was granted more uses of the IDE laser. To date his investigation is limited to 1 institution [redacted] location) and 225 subjects: 150 subjects (300 eyes) for low myopia (-0.5 to -6.75 diopters myopia plus up to -7 diopters astigmatism); 50 subjects (100 eyes) for high myopia (-7 to -15 diopters with up to -7 diopters astigmatism); and 25 subjects (50 eyes) for enhancements/retreatments of subjects treated prior to IDE approval (-0.5 to -15 diopters myopia with up to -7 diopters astigmatism). From the date the first patient was treated under the IDE, August 28, 1997, until this inspection [redacted] has treated 154 subjects (276 eyes) for high and low myopia and 24 subjects (23 eyes) for myopic enhancements. The figures were retrieved from the [redacted] Log which according to [redacted] represents all IDE patients treated to date.