[redacted]

4/19,20,23-30, 5/1-4,7,10/2001 [redacted]

[redacted] performs minor parts replacement and maintenance however, all major work is performed by [redacted] Maintenance records observed during the inspection do indicate that [redacted] is performing maintenance, repairs and calibrations.

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. According to [redacted] consultant, validation of the computer system is to be done by an outside firm and will be included with the submission

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 (diamond knife). 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.

[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. As of 11/2/98 his investigation is limited to **1 institution ([redacted]** 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).

According to a letter from the FDA to [redacted] dated 1/20/99 **EXHIBIT #1**, the investigation is still limited to one location, listed in bold above however, the population has grown to 1015 subjects (2030 eyes): 990 subjects (1980 eyes) for myopia (-0.5 to -15 D with up to -7 D astigmatism); and 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7D astigmatism).