2.0 RISK ANALYISIS

The risk analysis remains unchanged from that submitted with the original IDE. There are no emerging complications or adverse events that alter the risk analysis. The adverse event and complication rates remain low.

3.0 DEVICE CHANGES

The following device changes have occured since the last annual report:

- Sculpting device upgrade: The sculpting device component was replaced as a preventative measure. The sculpting device (manufactored by Skepsis) was upgraded to the latest model since the current model was no longer available. The software interface calls in the Nevyas treatment algorithm; hence, no changes have been made to the treatment algorithm.

4.0 CHANGES IN INVESTIGATIONAL PLAN

All reportable changes to the investigational plan have been previously submitted to the FDA for review and approval via amendments, revised versions of the protocol(s), or substudies.

5.0 PROGRESS TOWARDS PMA APPROVAL

It was previously recommended by FDA that only subjects treated with the new contration technique (as previously described) be included in the PMA. We have preliminarily selected the eyes treated between 2/19/98 through 1/22/99 as the cohort of eyes that will be used to support the safety and effectiveness of the device in the PMA submission. This group of eyes is comprised of:

- 125 eyes treated for low spherical myopia only (< -7.0 D MRSE);
- 346 eyes treated for low myopic astigmatism (< -7.0 D MRSE);
- 10 eyes treated for high spherical myopia only (≥ -7.0 D MRSE); and,
- 82 eyes treated for high myopic astigmatism (≥ -7.0 D MRSE).

Since there are less than 125 eyes in the high myopia subset, the initial PMA submission will only include data to support the indications of low spherical myopia and low myopic