b. You should supply scientific references applicable to the derived equation, and include all mathematical steps leading to the equation. You have not furnished the requested scientific references, nor the intermediate mathematical steps. Please provide this information.

c. You should provide an explanation of the reasons that D (power in diopters), and n (index of refraction of the cornea) do not appear in the ablation equation, and why the coordinate Y is undefined; no information has been provided explaining why the ablation equation has no D, or n dependence. As discussed previously, the explanation that Y is any spherical coordinate on the y axis is logically inconsistent.

d. You should identify the ablation axes for $c_1()$ and $c_2()$.

e. Please indicate how the derived equation is integrated into the device software to provide calculations that are required for the targeted corrections.

13. The theoretical fits to the profilometric data are based on 8th order polynomials. It is not clear what theory this procedure is based on and is apparently in qualitative disagreement with the data in the central 2 mm and outside the ablation zone. The appropriate theoretical fits should be to circular contours, since the ablations are supposed to approximate Munnerlyn's equations. Typically, one determines the theoretical mathematical ablation curve (i.e., the theoretical curve), employs hardware and software to approximate the mathematical curve (i.e., the programmed ablation curve), then measures the resultant ablation curve (i.e., the actual ablation curve in PMMA, for instance). It is not clear what is the theoretical curve to which you are trying to match your ablation curves (programmed and actual).

a. Please provide additional explanation regarding the theoretical ablation curves (mathematical equations) which you are trying to approximate with your hardware and software.

b. Please discuss how the programmed pattern described on pages 57-61 (Original IDE) and summarized in attachment 2.A-3 (Amendment 1, dated July 3, 1997) approximates the theoretical pattern described on pages 56-57 (Original IDE); plots of the programmed patterns versus the theoretical patterns would be helpful in this discussion.

Multifocality:

FDA 0 0027

14. Your ablation patterns for correcting myopia and astigmatism do not appear to be spherical and cylindrical, respectively, and, therefore, cannot provide a single dioptric