26

Letter to Industry Re: Lasers Oct. 10, 1996

NOTE: THE FOLLOWING IS AN UPDATED VERSION OF THE OCTOBER 8, 1996 LETTER WHICH CLARIFIES THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CONTACTS (SEE BOLDED TEXT AT END OF PAGE 2).

October 10, 1996

Dear Manufacturers and Users of Lasers for Refractive Surgery:

The Food and Drug Administration (FDA) is confident that you share our objective of providing the American public reasonable assurance that all lasers for refractive surgery are safe and effective, and looks forward to working with you to achieve that goal.

The purpose of this letter is to clarify which lasers and indication(s) are approved by FDA, and to provide direction on what clinicians should do if they have an unapproved laser or wish to employ an approved laser for a use that is not in the approved labeling.

As you know, the FDA approved applications for premarket approval (PMAs) from Summit Technology, Inc. and from VISX Inc. for their excimer≥ ≤lasers for the correction of mild to moderate myopia in patients with minimal astigmatism. Based on the submitted data, these models were approved for refractive correction only by photorefractive keratectomy (PRK) of the corneal surface. Data were not submitted to support the use of these lasers for laser assisted in-situ keratomileusis (LASIK), laser scrape, astigmatism, hyperopia, or multipass or multizone software algorithms. Currently, these are the only lasers approved by FDA for refractive correction and the only refractive indications for which they are approved. The dioptric ranges indicated in the PMA are based on data submitted by these companies in their applications. Data on higher myopia and astigmatism were not submitted, and therefore the approvals did not provide for their treatment. All other lasers being used for refractive surgery, however manufactured or obtained, should be regarded as investigational devices and patients should have the usual human subject protection of institutional review board (IRB) protection, informed consent and an IDE approval by FDA.

Because patients who receive laser treatment for the correction of refractive error have a right to expect that the laser device being used on their eyes is reasonably safe and effective, FDA required as part of the PMAs that patients be issued with a Patient Information Booklet which provides them with essential information about the likely outcome of refractive surgery on their eyes. This information includes success and failure rates, rates of adverse events, stability of correction, and other information needed for patients to make an informed decision.

On May 7 the FDA and the Federal Trade Commission (FTC) issued a joint letter to users of the VISX and Summit lasers. The purpose of that letter was to inform practitioners that advertising of legally marketed devices and PRK treatment was regulated jointly by FDA and FTC. The letter also discussed that the use of these lasers for other than their intended use was considered off-label. FDA has long maintained that practitioners must make decisions that will best serve their patients and that FDA does not seek to regulate the practice of medicine. Although uses such as