



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 29 2003

August 26, 2003

Office of Orphan Products Development (HP-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Addition Technology, Inc.
155 Moffett Park Drive, Suite B-1
Sunnyvale, California 94089-1330

Attention: Darlene Crockett-Billig
Regulatory Consultant

Dear Ms. Crockett-Billig:

Reference is made to your humanitarian use device (HUD) request of July 11, 2003, submitted pursuant to section 520(m) of the Federal Food, Drug, and Cosmetic Act for the designation of the INTACS[®] Prescription Inserts (request #03-0112).

We have completed the review of this application and have determined that the INTACS[®] Prescription Inserts qualify for Humanitarian Use Device (HUD) designation for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles, so that their functional vision may be restored and the need for corneal transplant procedure can potentially be deferred as required by Section 520(m) of the Federal Food, Drug, and Cosmetic Act.

Please refer to this letter as official notification of designation and congratulations on obtaining your HUD designation.

Sincerely yours,

Marlene E. Haffner, M.D., M.P.H.

Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development

CE APPROVED FOR KERATOCONUS

European Clinical Data Have Demonstrated That Intacs Are Safe And Effective, Improve Patients' Quality Of Vision And Appear To Stabilize The Diseased Cornea.

IMPROVED VISION:

- 78% Gained 2-11 Lines Of UCVA
- 74% Of Those 20/40 Or Better Gained 2-8 Lines Of BCVA
- 76% Reported Subjective Improvement In Vision Quality
- Statistically Significant Improvements In The Reduction Of Manifest Refraction, Astigmatism And Central Keratometry Readings

STABILIZED VISION:

- Intacs Flatten And Shift The Cone Centrally, Restructuring The Corneal Architecture To A Normal Prolate Shape
- Intacs Support The Structural Integrity Without Invading The Central Optical Zone

DEFER CORNEA TRANSPLANT:

- Intacs Placement Provide An Option To Defer PKP, Generally Recognized As The Final Course-Of-Action
- Intacs Restore Functional Vision By Allowing Most Patients To Be Effectively Corrected With Contact Lenses Or Glasses, If Needed

SAFETY:

- Intacs Keratoconus Safety Mirrors FDA Approved Clinical Studies For Myopia
- If Required, Intacs Can Be Removed And The Option For PKP Is Still Preserved



ADDITIVE PROLATE OPTICS