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Industry news in brief

FDA OKs corneal disease study for Intacs

SCOTTSDALE, Ariz. — Clinical Research and Statistics (CRS), a physician research group based here, and KeraVision Inc. (NASDAQ: KERA) announced approval to perform a study that will initially involve Intacs implantation in 20 keratoconus patients at four U.S. centers, with possibly more patients and centers to be added subject to Food and Drug Administration (FDA) review and approval of initial clinical results.

Under the FDA's conditional approval of an investigational device exemption, CRS surgeons will be able to test whether the prescription inserts can improve patients' vision by strengthening and reshaping corneas that have been damaged by keratoconus.

The CRS study may pave the way for Intacs prescription inserts to be used in therapeutic applications, in addition to the refractive applications previously approved by the FDA.

Physician-sponsored clinical studies of Intacs inserts for keratoconus have been underway in Europe since 1997. Early clinical results have been encouraging, although limited and preliminary. The company plans to apply this year for formal CE mark approval.

The keratoconus study is the first of three studies that the CRS physician group wants to conduct for