

PMA P010018

ViewPoint[®] CK System

The ViewPoint™ CK System/Conductive Keratoplasty (CK) Procedure is indicated for the reduction of previously untreated spherical hyperopia in patients 40 years of age or greater, who have 0.75 D to 3.25 D of cycloplegic spherical hyperopia, with less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 D to 3.00 D, and no more than 0.50 D difference between pre-operative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent (CRSE). Some regression of the initial effect following the CK procedure is observed over the long term.

The ViewPoint™ CK System achieves its effect through a procedure known as Conductive Keratoplasty (CK). The System delivers radio frequency (RF) energy into the corneal stroma via a stainless steel Keratoplast Tip to achieve the desired collagen shrinkage temperature. Depending on the amount of refractive effect intended, 8, 16, 24 or 32 treatment spots in up to three concentric rings (6, 7 and 8 mm diameters) are individually placed with the Keratoplast Tip. Energy is delivered for 0.6 seconds per treatment spot. The peripheral application of the treatment creates a band of tightening and results in a steepening of the central cornea.

The sponsor began the clinical studies of the device in 1999. The PMA Cohort of the final clinical trial involved 12 sites and 401 eyes of 233 subjects (233 primary eyes and 168 fellow eyes). Three hundred and fifty (350) eyes were seen at 6 months post-operatively, 340 eyes at 9 months, and 171 at 12 months.