FDA 510(k) Premarket Notification

K223700 BOSS™

CLEARED

Aug 16, 2024
613 days to decision

K223700 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k223700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Dec 12, 2022
Decision date	Aug 16, 2024
Days to decision	613 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intelon Optics, Inc.**
Location	Woburn, MA, US
Contact	Pavana Mysore Ganesh
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT05423041

A Prospective Clinical Trial Designed to Evaluate the Repeatability and Reproducibility of the Intelon BOSS(tm) System

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	34 patients (actual)
Study sites	1 site
Condition studied	Corneal Transplant; Corneal Crosslinking; Healthy Eyes
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 13, 2022
Sponsor	Intelon Optics, Inc (Industry)

Primary outcome

Analysis of variance in BOSS analysis to determine repeatability and reproducibility

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05423041