FDA 510(k) Premarket Notification

K203586 EndoSerter-PL

CLEARED

Feb 2, 2022
421 days to decision

K203586 · Product code: **OTZ** · Ophthalmic
Source: https://www.510kdatabase.net/k203586/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Graft Insertion Instrument For Endothelial Keratoplasty (OTZ)
Date received	Dec 8, 2020
Decision date	Feb 2, 2022
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corneagen, Inc.**
Location	Winston-Salem, NC, US
Contact	Tom Miller
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**K.Hodai Consulting, Inc.**
Contact	Omid Kodai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov