

K220032 iStent infinite Trabecular Micro-Bypass System, Model iS3Aug 2, 2022
209 days to decisionK220032 · Product code: **KYF** · Ophthalmic
Source: <https://www.510kdatabase.net/k220032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Valve (KYF)
Date received	Jan 5, 2022
Decision date	Aug 2, 2022
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Glaukos Corporation
Location	San Clemente, CA, US
Contact	David S. Fernquist
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT03639870**Investigation of the Glaukos® Trabecular Micro-Bypass System, Model iS3, in Subjects With Refractory Glaucoma**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	65 patients (estimated)
Study sites	1 site
Condition studied	Glaucoma
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 1, 2021
Sponsor	Glaukos Corporation (Industry)

Primary outcome**Primary effectiveness endpoint**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03639870510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220032/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026