FDA 510(k) Premarket Notification

K212631 Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses

CLEARED

Mar 17, 2022
210 days to decision

K212631 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k212631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Aug 19, 2021
Decision date	Mar 17, 2022
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Contamac, Ltd.**
Location	Littleton, CO, US
Contact	Rob McGregor
Website	http://www.contamac.com/
510(k) history	18 submissions · 18 cleared · 2002-2022

Contamac, Ltd. is the world's largest manufacturer of contact and intraocular lens materials. The company develops specialist polymers and biocompatible materials for medical applications, with a manufacturing facility in Littleton, US. Contamac does not manufacture finished lenses; instead, it supplies raw materials to lens manufacturers globally. Contamac has received FDA 510(k) clearances from total submissions since 2002. The company specializes exclusively in Ophthalmic devices, with its latest clearance in 2022. All submissions have been cleared, reflecting a strong...

REGULATORY CONSULTANT

Consulting firm	**Eyereg Consulting, Inc.**
Contact	Bret Andre

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