FDA 510(k) Premarket Notification

CLEARED

K062548 MODIFICATION TO OPTIMUM GP (OXYGEN PERMEABLE) DAILY WEAR CONTACT LENSES

Nov 1, 2006
63 days to decision

K062548 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k062548/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Aug 30, 2006
Decision date	Nov 1, 2006
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Contamac, Ltd.**
Location	Littleton, CO, US
Contact	MARTIN DALSING
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...