

K180616 OPTIMUM GP (rofluvocon D, roflurocon E) Daily Wear Contact Lens, HEXA100 (hexafocon A) Daily Wear Contact LensApr 25, 2018
48 days to decisionK180616 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k180616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Mar 8, 2018
Decision date	Apr 25, 2018
Days to decision	48 days
Third-party review	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...

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Device record: <https://www.510kdatabase.net/k180616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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