

**K182304 Hyper GP (tisilfocon A) Daily Wear Contact Lens**Nov 23, 2018  
91 days to decisionK182304 · Product code: **HQD** · Ophthalmic  
Source: <https://www.510kdatabase.net/k182304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Aug 24, 2018
Decision date	Nov 23, 2018
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contamac, Ltd.</b>
Location	Littleton, CO, US
Contact	Rob McGregor
Website	<a href="http://www.contamac.com/">http://www.contamac.com/</a>
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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