

K171575 ENFLU 18 (enfluocon A) Daily Wear Contact LensOct 24, 2017
147 days to decisionK171575 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k171575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	May 30, 2017
Decision date	Oct 24, 2017
Days to decision	147 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...
