

**K023349 CONTAFLEX GM3 58% (ACOFILCON A) SPHERICAL
SOFT CONTACT LENS FOR DAILY WEAR (CLEAR AND
TINTED, LATHE-CUT)**Dec 24, 2002
78 days to decisionK023349 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k023349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Oct 7, 2002
Decision date	Dec 24, 2002
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Contamac, Ltd.
Location	Littleton, CO, US
Contact	MARTIN DALRING
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...