

**K970312 CONTROLLED PROCESS RELEASE OF FLEXLENS
(HEFILCON A)**Apr 2, 1997
65 days to decisionK970312 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k970312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 27, 1997
Decision date	Apr 2, 1997
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Flexlens, Inc.
Location	Englewood, CO, US
Contact	KEVIN M RANDALL
510(k) history	4 submissions · 4 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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