FDA 510(k) Premarket Notification

K864543 SUNGLASSES

CLEARED

Mar 13, 1987
114 days to decision

K864543 · Product code: **HQY** · Ophthalmic
Source: https://www.510kdatabase.net/k864543/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sunglasses (non-prescription Including Photosensitive) (HQY)
Date received	Nov 19, 1986
Decision date	Mar 13, 1987
Days to decision	114 days
Third-party review	No

APPLICANT

Company	**Image of Hawaii**
Location	Waianae, HI, US
Contact	JIM BLAIR
510(k) history	1 submissions · 1 cleared · 1987-1987

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k864543/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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