

K972850 SUNGLASSESSep 17, 1997
47 days to decisionK972850 · Product code: **HQY** · Ophthalmic
Source: <https://www.510kdatabase.net/k972850/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sunglasses (non-prescription Including Photosensitive) (HQY) |
| Date received | Aug 1, 1997 |
| Decision date | Sep 17, 1997 |
| Days to decision | 47 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Indoptica, S.A. |
| Location | Pomona, CA, US |
| Contact | JOHN R HONEY |
| 510(k) history | 1 submissions · 1 cleared · 1997-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026