

K140368 FAMILY OF DISPOSABLE LENSESApr 29, 2014
74 days to decisionK140368 · Product code: **HKS** · Ophthalmic
Source: <https://www.510kdatabase.net/k140368/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prism, Gonioscopic (HKS) |
| Date received | Feb 14, 2014 |
| Decision date | Apr 29, 2014 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sensor Medical Technology, LLC |
| Location | North Reading, MA, US |
| Contact | MAUREEN O'CONNELL |
| 510(k) history | 3 submissions · 3 cleared · 2014-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140368/> 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 3, 2026