

**K010852 OSMED TISSUE EXPANDER**Aug 13, 2001  
145 days to decisionK010852 · Product code: **NFM** · Ophthalmic  
Source: <https://www.510kdatabase.net/k010852/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Expander, Tissue, Orbital (NFM)    |
| Date received         | Mar 21, 2001                       |
| Decision date         | Aug 13, 2001                       |
| Days to decision      | 145 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Iop, Inc.</b>                      |
| Location       | Malibu, CA, US                        |
| Contact        | JASON MALECKA                         |
| 510(k) history | 9 submissions · 8 cleared · 1989-2009 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010852/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026