

K113656 CAREGUIDE OXIMETERJul 26, 2012
227 days to decisionK113656 · Product code: **MUD** · Cardiovascular
Source: <https://www.510kdatabase.net/k113656/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter, Tissue Saturation (MUD) |
| Date received | Dec 12, 2011 |
| Decision date | Jul 26, 2012 |
| Days to decision | 227 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Reflectance Medical, Inc. |
| Location | Westborough, MA, US |
| Contact | Nandini Murthy |
| 510(k) history | 5 submissions · 5 cleared · 2012-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113656/> 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 6, 2026