

K123532 OCELOT PIXL CATHETERDec 14, 2012
28 days to decisionK123532 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k123532/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter For Crossing Total Occlusions (PDU) |
| Date received | Nov 16, 2012 |
| Decision date | Dec 14, 2012 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Avinger, Inc. |
| Location | Redwood City, CA, US |
| Contact | BABU PERIASAMY |
| 510(k) history | 25 submissions · 25 cleared · 2009-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123532/> 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 9, 2026