

K181642 B-Laser Atherectomy SystemOct 5, 2018
106 days to decisionK181642 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k181642/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Peripheral, Atherectomy (MCW) |
| Date received | Jun 21, 2018 |
| Decision date | Oct 5, 2018 |
| Days to decision | 106 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Eximo Medical, Ltd. |
| Location | Rehovot, IL |
| Contact | Yossi Muncher |
| 510(k) history | 7 submissions · 7 cleared · 2018-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181642/> 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 May 26, 2026