

K132190 EXPANDABLE LEMAITRE VALVULOTOME, OVER-THE-WIRE LEMAITRE VALVULOTOME

Aug 5, 2013
21 days to decision

K132190 · Product code: **MGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k132190/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Valvulotome (MGZ) |
| Date received | Jul 15, 2013 |
| Decision date | Aug 5, 2013 |
| Days to decision | 21 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | LeMaitre Vascular, Inc. |
| Location | Burlington, MA, US |
| Contact | Anna Kasseris |
| 510(k) history | 32 submissions · 32 cleared · 2003-2022 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132190/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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