

K162434 NC Gallant PTCA CatheterJan 19, 2017
141 days to decisionK162434 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k162434/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX) |
| Date received | Aug 31, 2016 |
| Decision date | Jan 19, 2017 |
| Days to decision | 141 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medinol, Ltd. |
| Location | Tel-Aviv, IL |
| Contact | MICHAL HERSHKOVITZ |
| 510(k) history | 6 submissions · 3 cleared · 1998-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162434/> 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 31, 2026