FDA 510(k) Premarket Notification

# K072770 TEMPORARY PACING LEAD, SERIES TBB, MODEL HELIOS (TM)

**CLEARED**

Jan 22, 2008
116 days to decision

K072770 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k072770/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Pacemaker, Temporary (LDF) |
| Date received | Sep 28, 2007 |
| Decision date | Jan 22, 2008 |
| Days to decision | 116 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Oscor, Inc.** |
| Location | Palm Harbor, FL, US |
| Contact | MILA DOSKOCIL |
| 510(k) history | 49 submissions · 46 cleared · 1979-2021 |