

K080106 SKINTACT PRE-WIRED ECG ELECTRODES WITH CONDUCTIVE ADHESIVEFeb 1, 2008
17 days to decisionK080106 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k080106/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Jan 15, 2008 |
| Decision date | Feb 1, 2008 |
| Days to decision | 17 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Leonhard Lang GmbH |
| Location | Stillwater, MN, US |
| Contact | ELAINE DUNCAN |
| 510(k) history | 17 submissions · 17 cleared · 2002-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080106/> 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 5, 2026