

**K884983 M55 K KARAYA GUM DISP. MICROTAPE ECG  
ELECTRODE, 55**Mar 9, 1989  
100 days to decisionK884983 · Product code: **DRX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k884983/>**SUBMISSION DETAILS**

---

|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received         | Nov 29, 1988                        |
| Decision date         | Mar 9, 1989                         |
| Days to decision      | 100 days                            |
| Third-party review    | No                                  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>S &amp; W Medico Teknik</b>          |
| Location       | Walker, MI, US                          |
| Contact        | LISBETH ISBRANDT                        |
| 510(k) history | 46 submissions · 46 cleared · 1984-1995 |

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884983/> 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