

**K923406 BIOSCOPE**Sep 22, 1993  
439 days to decisionK923406 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k923406/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 10, 1992
Decision date	Sep 22, 1993
Days to decision	439 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biotronik, GmbH &amp; Co.</b>
Location	Lake Oswego, OR, US
Contact	VICTOR CHEN
510(k) history	18 submissions · 17 cleared · 1989-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923406/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026