

**K844277 OMIKRON PACEMAKER 837 UNIPOLAR & 838 BIPOLAR**Feb 15, 1985  
102 days to decisionK844277 · Product code: **DXG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k844277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Nov 5, 1984
Decision date	Feb 15, 1985
Days to decision	102 days
Third-party review	No

**APPLICANT**

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Company	<b>Omikron Scientific, Ltd.</b>
Location	Walker, MI, US
Contact	SANDORD BROWN
510(k) history	4 submissions · 3 cleared · 1984-1991

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844277/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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