

**K801640 SORIN PULSE GENERATOR, MODEL #LIT-214**Oct 3, 1980  
78 days to decisionK801640 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k801640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 17, 1980
Decision date	Oct 3, 1980
Days to decision	78 days
Third-party review	No

**APPLICANT**

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Company	<b>Bentley Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.bentleyinstruments.com">https://www.bentleyinstruments.com</a>
510(k) history	55 submissions · 55 cleared · 1976-1993

Bentley Laboratories, Inc. is located in McHenry, US. The company has a historical record of FDA 510(k) device clearances spanning from 1976 to 1993. Bentley Laboratories received FDA 510(k) clearances from total submissions. The company specialized primarily in Cardiovascular devices, which represented approximately 80% of its regulatory submissions. Notable cleared devices included blood cardioplegia heat exchangers, venous reservoir bags, membrane oxygenators, and central venous catheters used in cardiac surgery and perfusion applications. The company is inactive and s...

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