

**K012906 ANIMEC, MODELS AM-2S-4 AND AM-2S-5**Oct 9, 2001  
41 days to decisionK012906 · Product code: **LGZ** · General Hospital  
Source: <https://www.510kdatabase.net/k012906/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Warmer, Thermal, Infusion Fluid (LGZ)
Date received	Aug 29, 2001
Decision date	Oct 9, 2001
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Elltec Co., Ltd.</b>
Location	Nagoya, JP
Contact	GENSHIRO OGAWA
510(k) history	2 submissions · 2 cleared · 2001-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012906/> 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 2, 2026