

**K971366 INCUWARMER**Jan 5, 1998  
266 days to decisionK971366 · Product code: **FMT** · General Hospital  
Source: <https://www.510kdatabase.net/k971366/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Apr 14, 1997
Decision date	Jan 5, 1998
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hill-Rom, Inc.</b>
Location	Batesville, TN, US
Contact	JAMES G CARPENTER
Website	<a href="http://www.hill-rom.com">http://www.hill-rom.com</a>
510(k) history	33 submissions · 33 cleared · 1986-2021

Hill-Rom, Inc. is a global medical device manufacturer specializing in hospital care equipment and patient handling solutions. The company operates with a manufacturing facility in Batesville, Indiana, and serves healthcare providers across multiple care settings including hospitals, surgical centers, and home healthcare environments. Hill-Rom has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on General Hospital devices, including patient beds, stretchers, warming systems, and fluid mana...

---