

**K040910 INFANT INCUBATOR, MODEL CHS-I1000**Apr 21, 2004  
13 days to decisionK040910 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k040910/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Apr 8, 2004
Decision date	Apr 21, 2004
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Choong Wae Medical Corp.</b>
Location	Marietta, GA, US
Contact	RONALD D ARKIN
510(k) history	2 submissions · 2 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040910/> 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 May 17, 2026