

**K801461 THERMA-SHIELD**Jul 28, 1980  
34 days to decisionK801461 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k801461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jun 24, 1980
Decision date	Jul 28, 1980
Days to decision	34 days
Third-party review	No

**APPLICANT**

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Company	<b>Olympic Medical Corp.</b>
Location	Mchenry, IL, US
510(k) history	37 submissions · 37 cleared · 1978-2008

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Device record: <https://www.510kdatabase.net/k801461/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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