

**K100488 IR EAR/FOREHEAD THERMOMETER MODE DX6635,  
DX6637, DTH1081**Jul 22, 2010  
153 days to decisionK100488 · Product code: FLL · General Hospital  
Source: <https://www.510kdatabase.net/k100488/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 19, 2010
Decision date	Jul 22, 2010
Days to decision	153 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Dongdixin Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	ZHIGANG ZHAO
510(k) history	25 submissions · 25 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100488/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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