

**K103061 BIOMATE STERILE ACUPUNCTURE NEEDLE**Jun 20, 2011  
245 days to decisionK103061 · Product code: **MQX** · General Hospital  
Source: <https://www.510kdatabase.net/k103061/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Acupuncture, Single Use (MQX)
Date received	Oct 18, 2010
Decision date	Jun 20, 2011
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biomate Medical Devices Technology Co., Ltd.</b>
Location	New Taipei City, TW
Contact	MICHAEL LEE
510(k) history	3 submissions · 3 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103061/> 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 June 19, 2026