

**K214004 CCBIO ASCPO Needle**Dec 13, 2022  
357 days to decisionK214004 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k214004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 21, 2021
Decision date	Dec 13, 2022
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cc Biotechnology Corporation</b>
Location	Tainan, TW
Contact	Edgar Yeh
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214004/> 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 26, 2026