

**K920049 MEDIX PC-305 NEONATAL INCUBATOR**May 21, 1993  
501 days to decisionK920049 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k920049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jan 6, 1992
Decision date	May 21, 1993
Days to decision	501 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medix I.C.S.A.</b>
Location	San Martin, Buenos Aires, AR
Contact	CARLOS GUERRA
510(k) history	6 submissions · 6 cleared · 1993-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920049/> 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 18, 2026