

**K970440 EKONIC DENTAL/MEDICAL MASK (MD 610)**Mar 27, 1997  
50 days to decisionK970440 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k970440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 5, 1997
Decision date	Mar 27, 1997
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ekonic Company, Ltd.</b>
Location	Carver, MA, US
Contact	WILLIE YUNG
510(k) history	1 submissions · 1 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970440/> 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 July 6, 2026