

**K971744 FLOOR MASK-EAR LOOP(BMR-15011)/FLOOR MASK-TIE(BMR-1503)**Jul 28, 1997  
77 days to decisionK971744 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k971744/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 12, 1997
Decision date	Jul 28, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Berkley Medical Resources, Inc.</b>
Location	Uniontown, PA, US
Contact	FRANK R DASTOLI
510(k) history	2 submissions · 2 cleared · 1996-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971744/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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