

**K944512 TRUZONE PFM DISPOSABLE MOUTHPIECE**Nov 2, 1994  
48 days to decisionK944512 · Product code: **BYP** · Anesthesiology  
Source: <https://www.510kdatabase.net/k944512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthpiece, Breathing (BYP)
Date received	Sep 15, 1994
Decision date	Nov 2, 1994
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Monaghan Medical Corp.</b>
Location	Mchenry, IL, US
Contact	JAMES A COCHIE
Website	<a href="https://www.monaghanmed.com">https://www.monaghanmed.com</a>
510(k) history	33 submissions · 33 cleared · 1976-2013

Monaghan Medical Corp. is a respiratory health medical device manufacturer based in McHenry, US. The company specializes in innovative aerosol drug delivery and respiratory management products. Monaghan Medical has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's portfolio is dominated by Anesthesiology devices, representing 91% of submissions. The latest clearance on record dates to 2013, reflecting the company's historical regulatory activity in respiratory care. The company's cleared devices include peak flow meters...

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