

K830086 4.5 F LITHOTRIPTOR ELECTRODEFeb 9, 1983
29 days to decisionK830086 · Product code: **FFK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k830086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Jan 11, 1983
Decision date	Feb 9, 1983
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Monaghan Medical Corp.
Location	Mchenry, IL, US
Website	https://www.monaghanmed.com
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...