

**K813389 ULTRASONIC FRAGMENTOR**Feb 4, 1982  
63 days to decisionK813389 · Product code: **HQE** · Radiology  
Source: <https://www.510kdatabase.net/k813389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE)
Date received	Dec 3, 1981
Decision date	Feb 4, 1982
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>Fibra Sonics, Inc.</b>
Location	Walker, MI, US
510(k) history	10 submissions · 10 cleared · 1980-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k813389/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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