

**K915634 FRESENIUS PD+ EXCHANGE DEVICE**Jul 1, 1993  
562 days to decisionK915634 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k915634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Dec 17, 1991
Decision date	Jul 1, 1993
Days to decision	562 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fresenius USA, Inc.</b>
Location	Walker, MI, US
Contact	TOM FOLDEN
510(k) history	38 submissions · 37 cleared · 1984-1999

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