

K032976 BIOVALVE MINIJECT NEEDLE-FREE INJECTION SYSTEM, MODEL FG-01-001Apr 16, 2004
205 days to decisionK032976 · Product code: **KZE** · General Hospital
Source: <https://www.510kdatabase.net/k032976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Fluid, Non-electrically Powered (KZE)
Date received	Sep 24, 2003
Decision date	Apr 16, 2004
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biovalve Technologies, Inc.
Location	Worcester, MA, US
Contact	SCOTT HUIE
510(k) history	3 submissions · 3 cleared · 2004-2005

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