

**K200103 BIOTEQ Drainage Catheter Set (One Step Type)**Oct 9, 2020  
266 days to decisionK200103 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k200103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 17, 2020
Decision date	Oct 9, 2020
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioteque Corporation</b>
Location	Taipei City, TW
Contact	Stella Hsu
510(k) history	3 submissions · 3 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200103/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026