

**K153128 Kolplast Cervical Sample Collection Kit**Jan 13, 2017  
442 days to decisionK153128 · Product code: **HHT** · Pathology  
Source: <https://www.510kdatabase.net/k153128/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatula, Cervical, Cytological (HHT)
Date received	Oct 29, 2015
Decision date	Jan 13, 2017
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kolplast CI SA</b>
Location	Itupeva- Sp, BR
Contact	DANIELA FERACIN
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153128/> 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 13, 2026