

**K083012 PAPCONE**Apr 9, 2009  
182 days to decisionK083012 · Product code: **HHT** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k083012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatula, Cervical, Cytological (HHT)
Date received	Oct 9, 2008
Decision date	Apr 9, 2009
Days to decision	182 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Otto Bock Pur Life Science GmbH</b>
Location	Duderstadt, Lower Saxony, DE
Contact	CHRISTIAN SCHULTE
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083012/> 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 June 23, 2026