

K861389 PAP SMEAR KITMay 2, 1986
18 days to decisionK861389 · Product code: **HHT** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k861389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatula, Cervical, Cytological (HHT)
Date received	Apr 14, 1986
Decision date	May 2, 1986
Days to decision	18 days
Third-party review	No

APPLICANT

Company	Intl. Cytobrush, Inc.
Location	Hollywood, FL, US
Contact	TENNY P TSE
510(k) history	4 submissions · 4 cleared · 1986-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861389/>; Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026