

K081522 BIO NUCLEAR DIAGNOSTICS (ENDO)CERVICAL SAMPLER FOR GYN CYTOLOGYDec 5, 2008
189 days to decision

K081522 · Product code: HHT · Obstetrics & Gynecology

Source: <https://www.510kdatabase.net/k081522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatula, Cervical, Cytological (HHT)
Date received	May 30, 2008
Decision date	Dec 5, 2008
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio Nuclear Diagnostics, Inc.
Location	Toronto, Ontario, CA
Contact	SURENDER CHOUDHRY
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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