FDA 510(k) Premarket Notification

K081522 BIO NUCLEAR DIAGNOSTICS (ENDO)CERVICAL SAMPLER FOR GYN CYTOLOGY

CLEARED

Dec 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