

**K050305 ONE STEP HCG PREGNANCY URINE TEST FORMATS:
STRIP, CASSETTE AND MIDSTREAM, MODELS BM-1-1, BM-1-2,
BM-1-3, BM-2-1, BM-2-2**

May 23, 2005
104 days to decision

K050305 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k050305/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Feb 8, 2005
Decision date	May 23, 2005
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bioscreen Medical, Inc.
Location	Mildred, PA, US
Contact	JIMMY LIANG
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k050305/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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