JUL 2 7 2000

K002049

510(k) Summary
(As Required by 21 C.F.R. §807.92)

Submitted by:	Carol Adiletto, M.S. Director of Clinical Affairs Selfcare, Inc. 200 Prospect Street Waltham, MA 02154 Phone 781.647.3900, x124, Fax 781.647.3939 e-mail: carol.adiletto@usa.invernessmedical.com
Date of summary	June 29, 2000
Device name	Inverness Medical™ Early Pregnancy Test
Common name	Early Pregnancy Test
Classification names	Regulation Number: 862.1155(a) Classification Name: Kit, Test, Pregnancy, hCG, Over the Counter
Predicate Device	The modified device is substantially equivalent to the previously cleared Selfcare Early Pregnancy Test (K955903).
Modifications	The primary modifications are changes to the specimen sample time, wick material and dimensions. Corresponding dimensional changes have been made to the housing and certain component positioning within the housing to accommodate the wide wick design.
Intended Use	The modified device has the same intended use as the legally marketed predicate device. The Inverness Medical™ Early Pregnancy Test is intended for use by lay consumers for the qualitative detection of hCG in urine as an aid in the detection of early pregnancy.
Technological Characteristics	The modified device has the same technological characteristics as the legally marketed predicate device employing monoclonal antibodies for immunochromatographic assay.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis. Other evaluations included laboratory studies for repeatability, sensitivity, and interferences, and field evaluations for professional and consumer accuracy. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 27 2000

Ms. Carol A. Adiletto, M.S.
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453

Re: K002049
Trade Name: The Inverness Medical™ Early Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: June 29, 2000
Received: July 3, 2000

Dear Ms. Adiletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known) K002049

Device Name The Inverness Medical™ Early Pregnancy Test

Indications for Use The Inverness Medical™ Early Pregnancy Test is intended for use by lay consumers for the qualitative detection of hCG in urine as an aid in the detection of early pregnancy.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Veronica J. Calvin for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002649

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)