MAY 25 1999

K991466

Section 5 - revised

510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Carol Adiletto
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
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Contact Person:

Carol Adiletto
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Summary Prepared:

April 22, 1999

Name of the device:

Early Ovulation Predictor (cassette)
Ovulation Predictor (cassette)

Classification name(s):

Ovulation Predictor (cassette) is a Class I device (21 CFR § 862.1485) for home use.

Classification of predicate device(s):

The Ovulation Predictor test is not materially different from the predicate ClearPlan® Easy ovulation tests that are manufactured by Unipath, Ltd., Bedford, UK,. and were cleared for use in the United States by K981271 and K894579.

Description of the device/intended use(s):

The Ovulation Predictor test is used for the qualitative measurement of LH and the detection of LH surge in a woman's urine as an aid in conception by accurately and reliably predicting ovulation. The Ovulation Predictor test is intended for use outside the body (*in vitro* diagnostic use) by women at home. The Ovulation Predictor test is an over the counter (OTC) device that will be sold under the name Inverness Medical Early Ovulation Predictor, and under various private labels as Early Ovulation Predictor or Ovulation Predictor.

Statement of How the Technological Characteristics of the Device Compare to the Predicate device:

The technological characteristics are the same because both devices are urine tests that measure LH immunochromatographically, and have the same safety and effectiveness. They have the same intended use, i.e. use by women as an aid in conception. The new device is intended to be used for the qualitative measurement of LH and the detection of LH surge in a woman's urine. The Ovulation Predictor is intended for use by women outside the body (*in vitro* diagnostic use) as an aid to conception.

Summary of Performance Data:

Laboratory and clinical studies tests demonstrate that Ovulation Predictor (cassette) provides equivalent performance to the ClearPlan® Easy ovulation test.

Both devices are 99% accurate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 1999

Carol Adiletto
Director of Clinical Affairs
SELFCARE, INC.
200 Prospect Street
Waltham, MA 02453-3457

Re: K991466
Trade Name: Early Ovulation Predictor (cassette)
Ovulation Predictor (cassette)
Regulatory Class: I
Product Code: CEP
Dated: April 26, 1999
Received: April 27, 1999

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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

Section 4

Indications for Use Statement

510(k) Number (if known): K 991466

Device Name: Early Ovulation Predictor (cassette)
Ovulation Predictor (cassette)

Indications for Use:

The Ovulation Predictor test is used for the qualitative measurement of LH and the detection of LH surge in a woman's urine as an aid in conception by accurately and reliably predicting ovulation. The Ovulation Predictor test is intended for use outside the body (*in vitro* diagnostic use) by women at home. The Ovulation Predictor test is an over the counter (OTC) device that will be sold under the name Inverness Medical Early Ovulation Predictor, and under various private labels as Early Ovulation Predictor or Ovulation Predictor.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991466

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use ✓
(Per 21 CFR 801.019)