



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 11 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Young Ho Choi
Director
Access Bio, Inc.
675 U.S. Highway 1
North Brunswick, NJ 08902

Re: k031052
Trade/Device Name: CareStart™ hCG One-Step Pregnancy Test
CareStart Plus – hCG One-Step Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: March 31, 2003
Received: April 16, 2003

Dear Mr. Young Ho Choi:

This SE letter corrects the earlier letter stamp dated June 13, 2003. The name of the device had the word Combo in the wording for the name. It has now been removed from the Device Name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

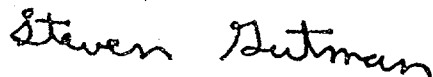
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Ver/ 3 - 4/24/96

Applicant: Access Bio Inc.

510(k) Number (if known): New Application

Device Name: CareStart™ hCG One-Step Pregnancy Test
CareStart Plus— hCG One-Step Pregnancy Test

Indications For Use:

CareStart™ hCG One Step Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by health care professionals.


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K031052

(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 801.109)

(Optional Format 1-2-96)