DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Howard M. Holstein
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004

Docket No.:99A-0436

Dear Mr. Holstein,

This is in response to your request, dated March 5, 1999, on behalf of Becton Dickinson and Company for an advisory opinion on whether certain state requirements are preempted as applied to the B-D A1c At-Home Test™ ("B-D At-Home Test").

Preemption of Device Requirements Under the Federal Food, Drug, and Cosmetic Act

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)) provides that no State or local government may establish or continue in effect any requirement with respect to a medical device that is different from or in addition to any requirement under the act applicable to the device, which relates to the safety or effectiveness of the device or any other requirement applicable to the device under the act. FDA's interpretive regulations concerning section 521 of the act are published in Title 21 of the Code of Federal Regulations Part 808 (21 CFR 808). According to the regulations, as upheld by the United States Supreme Court in Medtronic v. Lohr, 518 U.S. 470 (1996) (Lohr), preemption occurs only when there is a specific state or local requirement applicable to a particular device that is different from or in addition to a specific counterpart requirement that FDA has established for that particular device. 21 C.F.R. 808.1(d).

The B-D At-Home Test Clearance

On September 5, 1997, FDA issued an order (enclosed) finding the EZCHEK™/HBA Sample Collection Kit to be substantially equivalent to devices marketed in interstate commerce before 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 act. The device found to be substantially equivalent is a specimen collection kit for home use. The patient prepares a blood sample and mails it to a laboratory. The laboratory sends the results to the patient with a copy to a physician designated by the patient. Becton Dickinson acquired the 510(k) clearance and renamed the device the B-D A1c At-Home

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Test™ ("B-D At-Home Test"). The substantial equivalence order is a standard order and does not impose any specific requirements on the B-D At-Home Test.

The State Requirements

You state that a majority of states impose two types of prescription requirements that conflict with the over the counter (OTC) sale and use of the B-D At-Home Test. Some states require clinical laboratories to accept specimens only upon the order of authorized medical personnel. Other states require clinical laboratories to report test results only to persons authorized to order a test. You cite certain "illustrative" state laws. This advisory opinion will address only those state laws that you have specifically identified and of which you have provided FDA a copy. These are as follows:

California Business and Professions Code § 1288. This section provides that a clinical laboratory may accept assignments for tests only from person licensed under the provisions of law relating to the healing arts or their representatives. There are some exceptions to this requirement but they are not applicable to the B-D At-Home Test.

New York Compilation of Codes, Rules, and Regulations. Title 10, § 58-1.7(b). This section provides that clinical laboratories shall examine specimens only at the request of licensed physicians or other persons authorized by law to use the findings of laboratory examinations in their practice or performance of their official duties.

28 Pennsylvania Code §§ 5.41 and 5.47. Section 5.41 provides that specimens shall be accepted or collected from patients by a clinical laboratory only when tests are requested by a licensed member of the healing arts or other person authorized by statute. Section 5.47 provides that reports of clinical laboratory results shall only be provided to the person requesting the analysis.

Maryland Regulatory Code §§ 10.10.15 and 10.10.20. Section 10.10.15 provides that a medical laboratory may not perform a laboratory examination except upon the written or electronic authorization by a physician, dentist, podiatrist, or other person authorized by law to order an examination. Section 10.10.20 provides that a laboratory may only report the results of a test to the physician, dentist, or other authorized person that requested the test.

Florida Administrative Code Annotated, Rule 59A-7.028. This section provides that a laboratory may only perform tests upon the request of an "authorized person" and may only transmit the results to the "authorized person." It is not clear from the material that you submitted who is an "authorized person" for the purposes of this section. From the context, it appears that this would not include a patient.

FDA's Analysis

FDA's clearance of a premarket notification for the B-D At-Home Test based on a finding of substantial equivalence did not establish a "requirement" that the test be distributed over

the counter within the meaning of section 521 of the act. FDA simply allowed the device to be marketed OTC because it was substantially equivalent to a predicate device. Because FDA has not established any specific counterpart requirement within the meaning of section 521(a) of the act, the state requirements cited above are not preempted as applied to the B-D At-Home Test.

This situation is not comparable to the situation addressed in the advisory opinion issued to Robert P. Brady on December 18, 1996 and cited by you in your request for an advisory opinion. The Home Access™ HIV-1 Test Kit was cleared for marketing through a premarket approval order that established several specific requirements for the device. Among the requirements was that the device must comply with a specific protocol for its sale, distribution, and use. Any significant changes in that protocol would require a PMA supplement to be submitted to FDA for approval.

If you have any questions about this opinion, please contact Joseph M. Sheehan of our Center for Devices and Radiological Health at (301) 827-2974.

Sincerely yours,

Margaret Dotzel
Acting Associate Commissioner
for Policy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 1997

Donald R. Stone
Flexsite Diagnostics, Inc.
C/O McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K971919
EZCHEK™/HBA Sample Collection Kit
Regulatory Class: II
Product Code: LCP
Dated: August 15, 1997
Received: August 15, 1997

Dear Mr. Stone:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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/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