DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 4 2004

David B. Goldberg, Ph.D.
Director, Regulatory Affairs and Quality Systems
LifePoint, Inc.
1205 South Dupont Street
Ontario, CA 91761

Re: k041747
Trade/Device Name: IMPACT Test System; Saliva Test Module- Opiate
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, KHO
Dated: October 25, 2004
Received: October 26, 2004

Dear Dr. Goldberg:

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).

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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K041747/S001

Device Name: IMPACT Test System; Saliva Test Module – Opiate

Indications For Use: For *in vitro* diagnostic **workplace** use. The LifePoint® IMPACT® Test System Saliva Test Module (STM) for Opiate is a professional use single-drug test for the rapid determination of Opiate in human saliva. It provides qualitative screening results for Opiate at a cut-off value of 40 ng/mL. The disposable STM is used exclusively with the LifePoint IMPACT Test System instrument.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

Operators that may use this device are defined as individuals with no prior laboratory testing education or experience, and (1) have received training; a copy of the training checklist, which describes the topics to be covered during this orientation are included in the appendix of the Users Manual, (2) training includes a demonstration of the IMPACT test system and the use of Quality Check (CATALOG #2160) for monitoring and confirming the performance of the test system., (3) trainers monitor operators and confirm their competency and technique in running a test sample and quality control samples, (4) trainers confirm that operators can perform basic troubleshooting procedures, and their understanding of test results, including a discussion of the potential for false positive and false negative results and how to prepare a sample for shipment to a facility for confirmation testing, (5) have reviewed the information contained in the IMPACT Test System Quick Reference Guide and Users Manual., (6) have successfully taken a written exam to verify their competency and obtained a test score of at least 80% on the written examination provided in the appendix of the Users Manual, and (7) have access to assistance from an individual who is experienced in laboratory equipment, and who is familiar with the interpretation of drug testing results.

It is the responsibility of those organizations required to follow Department of Transportation (DOT) or Substance Abuse and Mental Health Services Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA authority.

Prescription Use_____ OR OTC Use X (Workplace)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041747