K003096

NOV 3 0 2000

510(k) Summary

FastPack™ Calibrators

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter name, address, contact	Qualigen, Incorporated 2042 Corte del Nogal Carlsbad, CA 92009	
	Telephone: Fax:	(760) 918-9165 (760) 918-9127
	Contact Person:	Dorothy Deinzer
	Date Prepared:	September 29, 2000
2. Device name	Proprietary name:	FastPack™ Calibrators
	Common name:	Calibrator
	Classification Name:	Calibrator, Secondary
3. Predicate device	Dade Behring Prostate Specific Antigen Calibrator	
4. Device description	***FastPack ™ Calibrators*** The FastPack™ Calibrators will be in liquid form, in vials, from which the user can directly remove calibrator. They will be formulated at two levels packaged together as a kit.	
5. Intended use	The FastPack™ Calibrators are intended to calibrate the FastPack™ Analyzer System when used for the quantitative determination of PSA in human serum and plasma.	

6. Comparison to Predicate Device

The following table compares the FastPack™ Calibrators with the Dade Behring Prostate Specific Antigen Calibrators.

Feature	Dade Behring Prostate Specific Antigen Calibrators	FastPack™ Calibrators
Intended Use	The PSA calibrator is an in vitro diagnostic product intended to be used to calibrate the Prostate Specific Antigen (PSA) method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.	For calibration of the FastPack™ Analyzer system when used for the quantitative determination of PSA in human serum and plasma.
Analytes	PSA-ACT	PSA
Matrix	Level 1 – Horse serum base Levels 2 through 5 – Bovine Serum Albumin	Bovine Serum Albumin
Form	Frozen Liquid	Liquid
Volume	1.0 mL	5.0 mL
Levels	5	2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 3 0 2000

Ms. Dorothy Deinzer
Director of Quality Assurance
and Regulatory Affairs
Qualigen, Inc.
2042 Corte del Nogal
Carlsbad, California 92009

Re: K003096
Trade Name: FastPack™ Calibrators
Regulatory Class: I
Product Code: JIT
Dated: September 29, 2000
Received: October 3, 2000

Dear Ms. Deinzer:

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

Attachment 4

Indications for Use Statement

510(k) Number K003096

Device Name FastPack™ Calibrators

Indications for Use The FastPack™ Calibrators are intended to calibrate the FastPack™ Analyzer system when used for the quantitative determination of PSA in human serum and plasma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maghsoudi

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003096

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