



DEC 20 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Professor L. Poller  
European Concerted Action on Anticoagulation  
Department of Pathological Sciences  
Stopford Building  
The University of Manchester  
Oxford Road  
Manchester M13 9PT, UK

Re: K991439  
Trade Name: Poller Calibrants  
Regulatory Class: II  
Product Code: GGN  
Dated: October 21, 1999  
Received: November 1, 1999

Dear Professor Poller:

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.

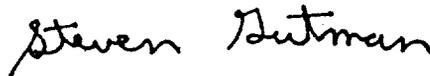
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

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  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K 991439

Device Name: "Potter Calibrants"

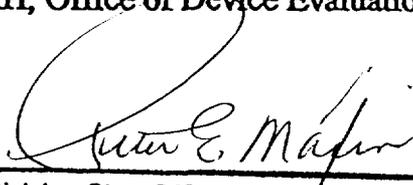
Indications For Use:

**INDICATIONS FOR USE**

- A. To provide calibration of local prothrombin time systems to accord with the WHO prothrombin time (PT) standardisation scheme ("the existing device").
- B. To avoid the need for local availability of an international reference preparation (IRP) for thromboplastin. IRP are not normally available except to national control laboratories and manufacturers.
- C. To avoid the need for the performance of the manual PT-technique required for conventional WHO calibrations. Most centres have now discarded the manual technique for automated procedures and are no longer skilled in the manual PT technique.
- D. To avoid the requirement for fresh plasma donations from 60 patients stabilised on warfarin treatment required for the conventional WHO calibrations.
- E. To facilitate serial calibration studies to check against drift of automated instruments or the effect of batch changes of commercial thromboplastin reagent.
- F. To provide a rapid result. A PT system calibration with the Calibrants takes about half an hour whereas a conventional WHO calibration requires several days. Five days are recommended by the revised 1999 WHO protocol.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 991439

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use