MAY 1 2 2003

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is: K030513 **CELL-DYN® 1800 System**
Submitted by	Abbott Laboratories 5440 Patrick Henry Drive Santa Clara, CA 95054
Contact Person	John Dean Phone (408) 567-3430 Fax (408) 567-3523
Date Prepared	February 14, 2003
Proprietary Name	CELL-DYN® 1800 System
Common Name	Automated Hematology Analyzer
Classification Name	Automated Differential Cell Counter (21 CFR 864.5220)
Predicate Device	Abbott CELL-DYN 1700 System, K870233
Device Description	The CELL-DYN 1800 System is a benchtop analyzer consisting of the main analyzer with data module, display station, and printer. The main analyzer, data module, and display station are housed in a single chassis. The printer is a stand-alone module. The CELL-DYN 1800 open sampler is equipped to aspirate blood from a collection tube that has been opened and is held under the open sample aspiration probe.
Intended Use	The CELL-DYN 1800 System has the same intended use as previously cleared for the CELL-DYN 1700 System, K870233. The CELL-DYN 1800 System is a multiparameter, automated hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories.

Similarities And Differences

The CELL-DYN 1800 System and the CELL-DYN 1700 System are similar in that:

a) Both systems accept open specimens presented manually by the operator.
b) Both systems automatically aspirate the specimen and present it for automated processing.
c) Both systems use microprocessors for systems control, data acquisition, and data analysis.
d) Both systems accept input from keyboard and send data output to: video screen, hard drive, and printer; and both systems provide RS232 Interface to an on-line LIS.
e) Both systems provide Dispersional Data Alerts, Suspect Parameter Messages, and Suspect Population Flags to assist in data review.
f) Both Systems use electrical impedance on the von Behrens Transducer for counting and sizing cells.
g) Both systems use LED Hemoglobin analysis.
h) Both systems use Volumetric Metering as the Reference ICSH Method.

The CELL-DYN 1800 System and the CELL-DYN 1700 System are different in that:

a) The CELL-DYN 1800 System uses Cyanide-Free differential lyse reagent, while the CELL-DYN 1700 uses a cyanide-containing lytic agent.
b) The CELL-DYN 1800 System is capable of inputting specimen information from a bar code through a hand held bar code scanner, while the CELL-DYN 1700 System does not have bar code scanning capabilities.
c) The CELL-DYN 1800 is capable of data output to both a dot matrix printer and an inkjet printer, while the CELL-DYN 1700 is only capable of data output to a dot matrix printer.
d) The CELL-DYN 1800 is a smaller and more compact system than the CELL-DYN 1700 System.
e) The CELL-DYN 1800 has a High Resolution Color Monitor (LCD), while the CELL-DYN 1700 has a High Resolution Color Monitor (CRT).
f) The CELL-DYN 1800 has a Patient Data Storage of 10,000 Run Cycles, while the CELL-DYN 1700 has a Patient Data Storage of 5,000 Run Cycles.

Clinical Study Protocol	The Clinical Study Protocol for the CELL-DYN 1800 is found in Attachment E.
Equivalency Data Summary	The CELL-DYN 1800 System is a multi-parameter, automated hematology analyzer for *in* vitro diagnostic use in clinical laboratories. The CELL-DYN 1800 System, which includes reagents and software, was compared in an in-house clinical trial to the CELL-DYN 1700 System. The data compiled supports the claim that the CELL-DYN 1800 System is substantially equivalent to the CELL-DYN 1700 System and includes data for background, correlation, precision, linearity, sensitivity and specificity, and carryover. The data supporting the claim that the CELL-DYN 1800 is substantially equivalent to the CELL-DYN 1700 is found in Attachment F.
Conclusion	The CELL-DYN 1800 System is substantially equivalent to the CELL-DYN 1700 (predicate device). The differences noted do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John Dean
Manager, Regulatory Affairs
Abbott Laboratories
5440 Patrick Henry Drive
Santa Clara, California 95054

MAY 12 2003

Re: k030513
Trade/Device Name: CELL-DYN® 1800 System
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: February 14, 2003
Received: February 19, 2003

Dear Mr. Dean:

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,

Steven Gutman

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

510(k) Number (if known): K030513

Device Name: CELL-DYN® 1800 System

Indications for Use:

The CELL-DYN 1800 System is an automated, multiparameter hematology analyzer designed to report sixteen parameters relating to the cells of EDTA-anticoagulated blood.

(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)

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030513