D. 510(K) SUMMARY

K030340

APR 11 2003

510K Summary for the AutoloGel Process Centrifuge

Submitter's Name and Address:	Cytomedix, Inc 1523 S. Bowman Road, Suite A Little Rock, AR 72211
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Contact Person:	Carelyn P. Fylling Vice President of Professional Services 218-547-4142 (o) 501-352-1184 (cell) fylling@eot.com
Date Summary Prepared:	January 20, 2003
Device Trade Name:	AutoloGel Process Centrifuge
Common Name:	General purpose centrifuge
Classification Name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050) – Class I
Product Code:	JQC [Centrifuges (Micro, Ultra, Refrigerated) for Clinical Use]
Substantial Equivalence:	The proposed device is substantially equivalent to other table-top centrifuges previously cleared by the FDA via the 510K Notification process. Two predicative centrifuges have been identified: Harvest Technologies, LLC., SmartPrep Centrifugation System (K991430) and 3i Models 7426 and 7437 CelSep Centrifuge System (K994148).
Device Description:	The AutoloGel Process Centrifuge consists of a table-top, non self-decanting, rotor spin centrifuge and processing disposables designed to allow for rapid automatic separation of plasma and red blood cells from a small volume of whole blood. The centrifuge spins at a maximum speed of 7200 rpms producing a maximum force of approximately 4227 g.
Intended Use:	The AutoloGel Process Centrifuge is designed to be used at the patient's point of care for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of the patient's blood (up to 60 ml).

Technological Characteristics: The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate devices. (See Table A)

Table A
Comparison of The AutoloGel Process Centrifuge with the Predicative Devices

Features	Cytomedix AutoloGel Process Centrifuge (This submission)	Harvest SmartPrep Centrifuge System K991430	3i CelSep K994148
Intended Use	To be used at the patient's point-of-care for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of the patient's blood (up to 60 ml).	To be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood. The plasma and concentrated platelets produced can be used for diagnostic tests.	For use in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample (50 – 60 ml of whole blood. The plasma and concentrated platelets produced can be used for diagnostic tests.
Principles of Operation	Separation based on density of liquids	Separation based on density of liquids	Separation based on density of liquids
Table-Top	Yes	Yes	Yes
Refrigerated	No	No	No
Swinging Bucket	No, fixed angle rotor	Yes	Yes
Automatic Decanting	No	Yes	No
Micro-Processor Controlled	Yes	Yes	Yes
User Programmable	No, preset by manufacturer	No, preset by manufacturer	Yes
Speed Control	Preset	Preset	Selectable
Acceleration and Braking	Current-controlled	Current-controlled	Current-controlled
Maximum RPM	7200 RPM	6000 RPM	3400 RPM
Maximum RCF	4227 g	3550 g	2050 g
Tube Capacity	Various sizes, maximum 60 ml	Two Processing Disposables (50 ml /disposable)	1 Disposable 60 ml/disposable
Lid Locking, Lid Holding	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 11 2003

Ms. Carelyn P. Fylling
Vice President for Professional Services
Cytomedix, Inc.
1523 S. Bowman Road – Suite A
Little Rock, AR 72211

Re: k030340
Trade/Device Name: AutoloGel Process Centrifuge
Regulation Number: 21 CFR 862.2050
Regulation Name: General purpose laboratory equipment labeled or promoted for a specific medical use
Regulatory Class: Class I
Product Code: JQC
Dated: January 31, 2003
Received: January 31, 2003

Dear Ms. Fylling

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the device's labeling:

> The safety and effectiveness of this device for in vivo indications for use has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, 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).

If you desire specific information about the application of other 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"(21 CFR 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,

S 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

B. STATEMENT OF INDICATIONS FOR USE

Applicant: Cytomedix, Inc.
510(k) Number (if known): K030340
Device Name: AutoloGel Process Centrifuge
Indications For Use:

The AutoloGel Process Centrifuge is designed to be used at the patient's point of care for the safe and rapid preparation of platelet-rich plasma (PRP) from a small sample of the patient's blood (up to 60 ml).

(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 K030340

[X] Prescription Use (per 21 CFR 801.109)

[ ] Over-the Counter Use

(Per 21 CFR 801.109)
(Optional Format 1-2-96)