FEB 1 2000

K994148

510(k) SUMMARY
3i CelSep Centrifuge System

Submitter's name and address:	Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, FL 33410
Telephone:	(561) 776-6819
Contact Person:	William G. Conety
Date Summary prepared:	1999 November 02
Device proprietary/trade name:	"CelSep" Centrifuge System
Common name:	General Purpose Centrifuge for Clinical Use
Classification Name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050)
Substantial Equivalence:	The proposed device is substantially equivalent to other table-top centrifuges previously cleared by the FDA via the 510(k) Notification process.
Device Description:	"CelSep" Centrifuge System consists of a table-top, non self-decanting, swinging bucket centrifuge and single-use processing disposable, designed to permit rapid and completely self-contained and safe separation of plasma and platelets from a small volume of whole blood. The centrifuge spins at a maximum speed of 3400 rpms at a maximum force of approximately 2050g.
Intended Use:	The 3i "CelSep" centrifuge System is designed 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 of blood.
Technological Characteristics:	"CelSep" centrifuge has the same technological characteristics and is similar in design and configuration compared with the predicate device (See Table 15a)

Table 15a

COMPARISON OF 3i "CelSep"
AND PREDICATE CENTRIFUGE

Features	3i "CelSep"	Predicate Centrifuge
Principle of operation	Separation based on density processing speed and equipment	Separation based on density processing speed and equipment
Table-Top Design	Yes	Yes
Refrigerated	No	No
Swinging Bucket	Yes	Yes
Automatic Decanting	No (1)	Yes
Micro-Processor Controlled	Yes	Yes
User Programmable	Yes	No
Speed Control	Selectable	Preset
Acceleration/breaking	Current-controlled	Current-controlled
Maximum RPM	3400 RPM	6000g
Maximum RCF	2050 RPM	3550g
Processing capacity	1 disposable 60ml/disposable	2 disposables 50ml/disposable
Lid Locking/Holding	Yes	Yes
Imbalance Detector	No (2)	Yes
Construction	Anti-rotational, metal housing and rotor	Anti-rotational, metal housing and rotor

(1) The "CelSep" centrifuge is not automatic decanting by design. The processing disposable is completely self-contained and is manually, pneumatically decanting.

(2) No imbalance detection feature is required by "CelSep" due in part to the lower speeds required for processing.

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 2000

Mr. William G. Conety
Regulatory Affairs
Implant Innovations, Inc.
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K994148
Trade Name: 3i "CelSep" Centrifuge System
Regulatory Class: I
Product Code: JQC
Dated: December 1, 1999
Received: December 8, 1999

Dear Mr. Conety:

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

510(k) Number: K 994148

Device Name: 3i "CelSep" Centrifuge System

INDICATIONS FOR USE:

The 3i "CelSep" Centrifuge System, is designed for use in the clinical laboratory or intra-operatively at point-of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60ml) of whole blood.

The plasma and concentrated platelets produced can be used for diagnostic tests.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 994148

Prescription Use: ✓ OR Over the counter use: _____
(Per 21 CFR 801.109)