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SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Disposable Semi-Automated Temno® Biopsy Device

Sponsor:	Allegiance Healthcare Corporation 1500 Waukegan Road MPWM McGaw Park, IL 60085
Regulatory Affairs Contact:	Sharon Nichols
Telephone:	(847) 785-3311
Date Summary Prepared:	December 2002
Product Trade Name:	Disposable Semi-Automated Temno® Biopsy Device
Common Name:	Disposable Biopsy System
Classification:	Class II per 21 CFR §876.1075, Instrument, Biopsy
Predicate Device:	Disposable Semi-Automated Temno® Biopsy Device
Description:	Needles are permanently attached to an automated device comprised of a spring that activates a stylet and cannula in a specified cutting sequence. The needle cuts and traps the tissue samples, which are substantially equivalent to samples obtained with similar devices currently in the market.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Disposable Semi-Automated Temno® Biopsy Device

Intended Use:	The Disposable Semi-Automated Temno® Biopsy Device is a system used for tissue sampling from several different organs, including, but not limited to, the Kidney, Liver, Breast and Prostate.
Substantial Equivalence:	The Disposable Semi-Automated Temno® Biopsy Device is substantially equivalent to the Temno® Biopsy Device in that: - Intended use is the same - Performance attributes are the same
Summary of testing:	All materials used in the manufacturing of the Disposable Semi-Automated Temno® Biopsy Device have been evaluated as outlined in the ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The materials were found to be acceptable for this intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2003

Ms. Sharon Nichols
Regulatory Affairs Manager
Allegiance Healthcare
1500 Waukegan Road
MCGAW PARK IL 60085

Re: K024120
Trade/Device Name: Temno® Biopsy Needle
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: December 13, 2002
Received: December 16, 2002

Dear Ms. Nichols:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Allegiance
a Cardinal Health company

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

510(k) Number (if known): K024120

Device Name: Disposable Semi-Automated Temno® Biopsy Device

Indications For Use: This biopsy device is used to remove, by cutting, a specimen of tissue for microscopic evaluation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lepore
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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024120