

10. **SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990).

**Date of Summary Preparation:** January 15, 1997

**Distributor:** Pharmacia & Upjohn

**Manufacturer:** Pharmacia & Upjohn AB  
S-751 82 Uppsala, Sweden

**Company Contact Person:** Shelley A. Beadle  
Pharmacia & Upjohn  
Director, Regulatory Affairs  
9200-298-109  
7000 Portage Road  
Kalamazoo, MI 49001-0199

**Device Names:** MasterCAP AM 5.0  
MasterCAP RM 5.0

**Common Name:** Software programs for assay and request management designed to support the set up of in vitro diagnostic assay runs with Pharmacia CAP System diagnostic equipment, which includes pipetting and diluting systems for clinical use.

**Classification:**

Note: MasterCAP AM and MasterCAP RM are software programs which support the functions of diagnostic equipment classified as "JQW Pipetting and Diluting System for Clinical Use".

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
MasterCAP AM 5.0	JQW	I	862.2750
MasterCAP RM 5.0	JQW	I	862.2750

**MasterCAP AM/RM 5.0 510(k) Submission**  
**Section 10. Summary of Safety and Effectiveness**

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**Substantial Equivalence to:**

MasterCAP AM Version 1.12  
UniCAP 100 RM Software

**Intended Use Statements:**

1. MasterCAP AM 5.0 is a software tool for Assay Management designed to support the set up of an in vitro diagnostic assay run. It is designed to be used with Pharmacia CAP System diagnostic equipment and related devices. It is run either in Microsoft Windows, 3.x, or Windows '95 Environment.

MasterCAP AM 5.0 handles sample lists, and creates worklists for the related Pharmacia & Upjohn diagnostic equipment. MasterCAP AM 5.0 also evaluates and calculates the assay results and generates laboratory reports. It can import and export results to main frame computers.

MasterCAP AM 5.0 includes a driver function which can send and receive patient data from UniCAP 100 diagnostic equipment.

2. MasterCAP RM 5.0 is a software tool for Request Management designed to be used together with MasterCAP AM 5.0. MasterCAP RM 5.0 includes a database and provides features for request management and data storage. MasterCAP RM handles requests and creates sample lists to be used in MasterCAP AM. When the data are evaluated, MasterCAP RM collects the results and generates a result report for each request. MasterCAP RM can store requests, requester information and test panels, and also provides backup and restore functions.

## MasterCAP AM/RM 5.0 510(k) Submission

### Section 10. Summary of Safety and Effectiveness

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#### General Description:

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1. MasterCAP AM 5.0 is a software tool for assay management designed to support the set up of an in vitro diagnostic immunoassay. It is designed to be used with Pharmacia CAP System diagnostic equipment and related devices. It is run either in Microsoft Windows, 3.x or Windows '95 Environment. The following Pharmacia CAP System diagnostic equipment and related devices may be used with MasterCAP AM: AutoCAP, Positioning Guide 96, RoboCAP Version 2.0, Fluorocount 96, Assay Washer 96, UniCAP 100.

When using the UniCAP 100 Device Driver Function of MasterCAP AM with UniCAP 100, you can transfer sample list data to, and import evaluated assay results from, one or more connected UniCAP 100 devices.

MasterCAP AM 5.0 software directs the diagnostic equipment to perform the following functions:

- \* import sample lists from a main frame computer or enter the information manually
- \* create an assay run
- \* distribute samples and tests
- \* process an assay
- \* collect raw data
- \* evaluate and calculate the results
- \* export the results to the main frame computer
- \* define assay methods and method groups

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2. MasterCAP RM 5.0 is a software tool for Request Management designed to be used with MasterCAP AM 5.0 for laboratories running in vitro diagnostic assays. MasterCAP RM includes a database and provides features for request management and data storage. MasterCAP RM handles requests and creates sample lists to be used in MasterCAP AM. When the data are evaluated, MasterCAP RM collects the results and generates a result report for each request. MasterCAP AM and MasterCAP RM are designed to be used with Pharmacia CAP System and UniCAP 100 diagnostic equipment and related devices.

MasterCAP RM can perform the following functions:

- \* create sample lists
- \* store requests, requester information and test panels
- \* create laboratory, result and patient test reports
- \* perform database queries
- \* provide backup and restore functions

**Device Comparison:**

Pharmacia CAP System is a complete modular system for in vitro diagnostics of allergy and other clinical areas. The system is based on ImmunoCAP technology and includes reagents, information and assay management software and automated processing equipment.

MasterCAP AM 5.0 and MasterCAP RM 5.0 are updates of previous versions of information management software designed to support the set up and management of in vitro diagnostic assays using Pharmacia CAP System and related diagnostic equipment.

MasterCAP AM 5.0 is substantially equivalent to MasterCAP AM 1.12, and MasterCAP RM 5.0 is substantially equivalent to UniCAP 100 RM software. Several improvements have been made to the updated software resulting in more convenient and versatile software.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 30 1997

Karen E. Matis  
• Regulatory Affairs Manager  
Pharmacia & Upjohn  
5094 St. Andrew Drive  
Westerville, Ohio 43082

Re: K970420  
MasterCAP AM 5.0/MasterCAP RM 5.0  
Regulatory Class: II  
Product Code: JQW  
Dated: June 6, 1997  
Received: June 9, 1997

Dear Ms. Matis:

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 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 (Pre-market 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 requirement, 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 pre-market 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.

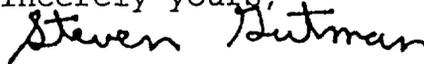
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsmamain.html>".

Sincerely yours,



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

**MasterCAP AM/RM 5.0 510(k) Submission**  
**Section 1. Intended Use Statements**

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510(k) Number : 6970420

Device Name: MasterCAP AM 5.0

Indications For Use:

MasterCAP AM 5.0 is a software tool for Assay Management designed to support the set up of an in vitro diagnostic assay run. It is designed to be used with Pharmacia CAP System diagnostic equipment and related devices. It is run either in Microsoft Windows, 3.x, or Windows '95 Environment.

MasterCAP AM 5.0 handles sample lists, and creates worklists for the related Pharmacia & Upjohn diagnostic equipment. MasterCAP AM 5.0 also evaluates and calculates the assay results and generates laboratory reports. It can import and export results to main frame computers.

MasterCAP AM 5.0 includes a driver function which can send and receive patient data from UniCAP 100 diagnostic equipment.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia A. Bernhart (for AUM)  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number 6970420

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

MasterCAP AM/RM 5.0 510(k) Submission  
Section 1. Intended Use Statements

510(k) Number: 15970420

Device Name: MasterCAP RM 5.0

Indications For Use:

MasterCAP RM 5.0 is a software tool for Request Management designed to be used together with MasterCAP AM 5.0. MasterCAP RM 5.0 includes a database and provides features for request management and data storage. MasterCAP RM handles requests and creates sample lists to be used in MasterCAP AM. When the data are evaluated, MasterCAP RM collects the results and generates a result report for each request. MasterCAP RM can store requests, requestor information and test panels, and also provides backup and restore functions.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 15970420

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

Optional Format 1-2-96)