K990310

AUG 30 1999

Charter Medical, Ltd

3948-A West Point Boulevard
Winston Salem, NC 27103
Telephone 336 768-6447
Facsimile 336 774-1750

1805 Swarthmore Avenue
Lakewood, NJ 08701
Telephone 732 901-9400
Facsimile 732 901-9405

SECTION 1.0 – 510(k) SUMMARY
Charter Medical, Ltd. 40 Micron Filter (Code MP450)

Applicant Name	Charter Medical, Ltd.
FDA Registration Number	2246665
Address	1805 Swarthmore Avenue Lakewood, NJ 08701
Contact Person	K. Alice Preville, Director Quality Assurance
Telephone	(732) 901-9400, Extension 17 (voice mail), Extension 23 (operator)
FAX	(732) 901-9405

Proposed Device

Nomenclature

a. Trade Name	Charter Medical, Ltd. MP450 (40 Micron Filter) Trademark is to be determined
b. Common Name	40 Micron Filter
Description	40 micron filter offered both as a stand alone device and as an integral component of a Y-Blood Administration Set.
Intended Use	To remove microaggregates and particulate debris from whole blood and red blood cells (RBCs) during infusion.
Predicate Device	SQ™40S 40-Micron Screen Filter manufactured by PALL Biomedical Products Company was determined by FDA to be substantially equivalent in July 1981 (Ref: K811985)

Summary of Technological Characteristics of New Device to Predicate Device

The device is substantially equivalent (as defined in Section 360c(I)(1)(A)(ii) of the Federal Food, Drug and Cosmetic Act) in performance to, in that it is as safe and effective as, the predicate device, as determined by flow rate, effect of filtration on blood constituents (white blood count, red blood count, hemoglobin, and hematocrit), and hold-up volume.

Materials used to manufacture the device were assessed in respect to biocompatibility using methods specified in ISO Standard 10993-1 and were found to be acceptable for intended use.

In addition to the referenced comparative studies, physical testing (i.e. housing integrity, media integrity, filter cleanliness, removal characteristics and security of attachments) support that the device is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 1999

Mr. David Heagle
R & D Manager
Charter Medical Limited
1805 Swarthmore Avenue
Lakewood, New Jersey 08701

Re: K990310
Trade Name: Charter Medical, Ltd. MP450(40 Micron Filter)
Regulatory Class: II
Product Code: CAK
Dated: August 9, 1999
Received: August 12, 1999

Dear Mr. Heagle:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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" (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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990310

510(k) Number (if known): K990310

Device Name: Charter Medical, Ltd. 40 Micron Filter (Code MP450)

Indications for Use:

Single use device for the removal of microaggregate and particulate debris from whole blood and red blood cells (RBCs) during infusion.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990310

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)