REGISTRATION NO.: 1039865
FOR: 1995

OWNER / OPERATOR NO.: 1039865

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT

NOTE: This form is authorized by Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2) (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001

REGISTERED ESTABLISHMENT

HOWARD INSTRUMENTS, INC.
4749 APPLETREE LANE
TUSCALOOSA, AL
35405 UNITED STATES

OWNER / OPERATOR

HOWARD INSTRUMENTS, INC.
4749 APPLETREE LANE
TUSCALOOSA, AL
35405 UNITED STATES

OFFICIAL CORRESPONDENT

JACK W. HOWARD
HOWARD INSTRUMENTS, INC.
4749 APPLETREE LANE
TUSCALOOSA, AL
35405

ESTABLISHMENT TYPE INITIAL DISTR
REPACK/RELABEL MANUFACTURER
REBUILD/REFURB

Detach Part 1 and Keep as Proof of Registration.
Complete and Return Part 2.
Detach and Refer to Part 3 for Specific Instructions.

Form FDA 2891a (12/83) Part 1 — Keep for Your Records Form Approved: OMB No. 0910-0059 Expiration Date: 03-31-96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Certificate for Products for Export

The Food and Drug Administration certifies that the products as described below are subject to its jurisdiction. Products which are legally distributed in accordance with the Federal Food, Drug, and Cosmetic Act within the United States may be exported without restriction.

21 CFR 820 of the Food and Drug Administration regulations requires the manufacturer to follow Good Manufacturing Practices. The plant in the United States where these products are manufactured is subject to periodic inspections by the Food and Drug Administration. A review of our records revealed no ongoing or pending regulatory actions against the following described products or plant location.

PRODUCTS	MANUFACTURING PLANT LOCATION
James Surgical System:	O.R. Specialties, Inc. 4749 Appletree Tuscaloosa, Alabama 35405
Vitrectomy Pack; #5120	
Jumper Pack; #203	
C-Mate; #CMV 1001	
Vitreous Cutter; #J-225	
Disposable Light Pipes; LP-1000-O, LP-1000-D, LP-1000-M	
Disposable Infusion Cannulae	
Corneal Trephines	

Eric Latish, Chief
Regulatory Guidance Branch
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 10th day of December, 1992.

Fleadia R. Farrah

FLEADIA R. FARRAH
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires September 11, 1994

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health