

K020959
143

03/18/02

Page 7a

JUN 19 2002

10. 510(k) Summary
Date March 18, 2002
Manufacturer: Not applicable at time of submission. Established
Registration will be submitted upon determination of
manufacturer
Owner: Sol Weiss, M.D.
7012 Reseda Boulevard
Suite A
Reseda, California 91335
Contact Person: Sol Weiss, M.D.
Device Trade Name: Glo- Spec I, II and III
Common Name: Connectors
Classification Name: Connector for devices (accessory to #12859 and other
manufacturers)
Regulatory Reference: 884.4530(17)

Description:

- The devices are made of injected molded parts
- Does not require assembly (simple product)
- Has vents to allow heat to escape
- No contact with body surfaces
- Has interlocking cone for device attachment
- The device is for single use only

510(k) Summary

Intended use:

- The intended use is interconnection of devices for transmission of light, hold suction tubes and instruments for other manufacturers
- The intended use is to illuminate area of view

Physical / Technical Comparison:

- Have the same intended use of transmitting light, hold suction tubes and instruments of other manufacturers
- Manufactured through injection molding
- Made with same materials
- Maintain same rigidity of part
- Both have clear plastic
- Both have windows that allow heat to escape

Differences:

- Attaches to upper blades of speculums and retractors to keep viewing clear
- Rests in the upper blades of Nu-Spec D and other manufacturer's speculums and retractors
- Does not alter the utilization, safety or efficacy of the Nu-Spec D while affording light for visualization
- Glo-Spec I, II and III portable connector has no body or membrane contact. Kleenspec connector as part of the handle has contact with the body surface.
- Glo-Spec I, II and III portable connector will allow for other different light sources to be used (i.e. penlights, etc.) Welch Allyn's Kleenspec only permits their transformer and equipment as a light source.
- Glo-Spec I, II and III portable connector place is above and out of area where bleeding may contaminate this device

K020959

3073

03/18/02

Page 7c

Performance Summary:

- Constructurally equivalent to the Welch Allyn's Kleenspec, and other predicate devices which have already been subjected to millions of applications

The Glo-Spec I, II and III complies with all acceptance criteria listed above.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Sol Weiss, M.D.
Sol Weiss, M.D., Inc.
7012 Reseda Boulevard, Suite A
RESEDA CA 91335

Re: K020959
Trade/Device Name: Glo-Spec I, II, and III
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized
manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: March 18, 2002
Received: March 25, 2002

Dear Dr. Weiss:

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.

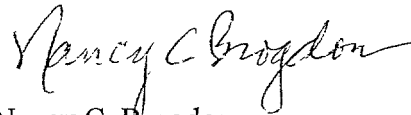
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020959

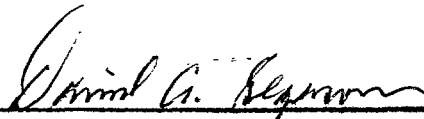
Device Name: Glo-Spec™ I, II and III

Indications for use:

The intended uses are interconnection of devices for transmission of light, hold suction tubes and instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices K020959
510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)