JUN 30 1998

stryker®

4100 East Milham Avenue
Kalamazoo, MI 49001
(616) 323-7700 (800) 253-3210

K981717

Premarket Notification 510(k) Summary
StrykerIlluminated Retractor,
a modification of the Stryker Knifelight Submission
Summary Prepared: 6/9/98

Device Name:

Classification Name:	Surgical Instrument Illuminated Retractor Surgical Instrument Light
Common/Usual Name:	Illuminated Retractor
Proprietary Name:	Stryker Illuminated Retractor

Device Sponsor:

Stryker Corporation
Instruments Division
4100 East Milham Avenue
Kalamazoo, MI 49001
Registration No: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker Illuminated Retractor is a manual surgical instrument with an integrated light source that will be sold separately as a single use only device. This can be used with the Knifelight to facilitate ligament or tissue division, or it can be used by itself to retract soft tissue.

The Stryker Illuminated Retractor is equivalent to existing marketed products by companies such as Ruggles and Stryker. Intended use, function, and safety risks are all substantially equivalent.

The Stryker Illuminated Retractor does not raise any new safety and efficacy concerns when compared to similar legally marketed devices. Therefore, the Stryker Illuminated Retractor is substantially equivalent to these existing devices.

Nicole Petty
Regulatory Affairs Representative
Stryker Instruments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Ms. Nicole Petty
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K981717
Trade Name: Stryker Illuminated Retractor
Regulatory Class: II
Product Code: FTD
Dated: May 12,1998
Received: May 15, 1998

Dear Ms. Petty:

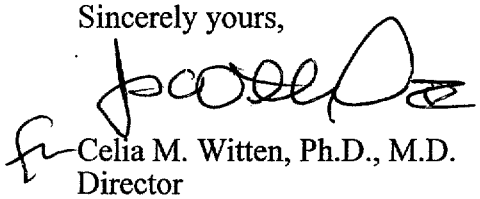
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981717

Device Name: Stryker Illuminated Retractor

Indications For Use:

The Illuminated Retractor is a manual surgical instrument with an integrated light source that will be sold separately as a single use only device. This can be used with the Knifelight to facilitate ligament or tissue division, or it can be used by itself to retract soft tissue.

(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 General Restorative Devices
510(k) Number K981717

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)