



K 980686

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990
Aesculap HiLan Motor System for Neurosurgery
February 20, 1998

Submitted by: Aesculap[®], Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Mary Ellen Holden Phone: (650)876-7000 x348
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Product: Aesculap HiLan Motor System for Neurosurgery
Common Name: Pneumatic Cranial Drill Motor

Device Description

The HiLan Motor System for Neurosurgery consists of a small hand held motor, an air hose, a foot control, a pneumatic motor hose, and various cranial handpieces (craniotome and perforator). The system components connect to each other via a proprietary coupling system.

Intended Use

Aesculap's HiLan Motor System for Neurosurgery is a pneumatic motor system intended for use in surgical procedures to provide power to operate removable cutting tools or drill bits on a patients skull. It is indicated for use in neurosurgery.

Technological Characteristics

The HiLan Motor System for Neurosurgery is identical in all technological characteristics to the HiLan Pneumatic Motor System which was cleared in K973736.

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's HiLan Motor System for Neurosurgery is manufactured in accordance with ISO and German Din Standards. Furthermore, Aesculap AG has received ISO 9001 certification.

Substantial Equivalence

Aesculap's HiLan Motor System for Neurosurgery shares similar features and function with corresponding devices distributed by Aesculap , Hall/Zimmer and Midas Rex.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1998

Ms. Mary Ellen Holden
Regulatory Associate
Aesculap, Inc.
1000 Gateway Blvd.
South San Francisco, California 94080

Re: K980686
Trade Name: Aesculap Hilan Motor System
Regulatory Class: II
Product Code: HBB
Dated: February 20, 1998
Received: February 23, 1998

Dear Ms. Holden:

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.

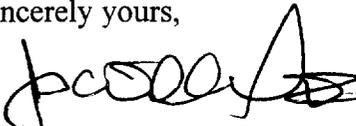
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,


f 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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K980686

Device Name:

Aesculap HiLan Motor System for Neurosurgery

Indication for Use:

Aesculap's HiLan Motor System for Neurosurgery is a pneumatic motor system intended for use in surgical procedures to provide power to operate removable cutting tools or drill bits on a patient's skull. It is indicated for use in neurosurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number

K980686