

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. 807.92.

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
Regulatory Engineer
Radionics Software Applications, Inc,
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
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This summary was prepared on August 12, 1999.

- 2.0 The name of the device is the Cosman Robert Wells Functional Probe Microdrive (CRW-FMD). The common name is microdrive for stereotaxic frame, and it is classified as a stereotaxic instrument.
- 3.0 The CRW-FMD is substantially equivalent to the Microdrive for Probes, an accessory for the Todd Wells Stereotaxic Guide that was commercially available prior to May 28, 1976.
- 4.0 The CRW-FMD is designed for the precise depth control of probes during stereotactic neurosurgical procedures. The CRW-FMD is mounted to a stereotaxic frame, and manually operated to advance a probe along the z-axis of a stereotactic trajectory. The main components of the system are: guide block base, stanchion probe holder, drive stanchion, drive box, digital display, and cable
- 5.0 The CRW-FMD like its predicate is intended for the precise depth control of probes during stereotactic neurosurgical procedures.
- 6.0 The technological characteristics are the same or similar to those found with the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

Mr. Kevin J. O'Connell
Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K992721
Trade Name: Cosman Robert Wells Functional Probe Microdrive
Regulatory Class: II
Product Code: HAW
Dated: August 12, 1999
Received: August 13, 1999

Dear Mr. O'Connell:

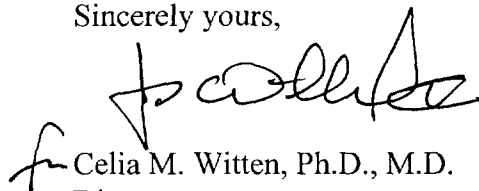
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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

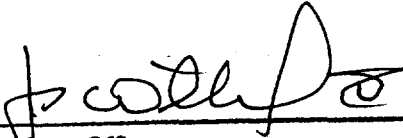
Enclosure

510(k) Number (if known): K992721

Device Name: Cosman Robert Wells Functional Probe Microdrive

Indications for use: For the precise depth control of probes during stereotactic neurosurgical procedures.

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


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992721

PRESCRIPTION USE ☒

OR

Over-The-Counter Use
☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)