K102802

INTEGRA™ Electrode Tunneling Needle

510(k) Summary

NOV 2 3 2010

Submitter's Name and Address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536 USA

Contact Person:

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Device Information

Proprietary Name:	INTEGRA™ Electrode Tunneling Needle
Common Name:	Tunneling Needle, Tunneler
Classification Name:	Cortical Electrode (21CFR 882.1310)
Device Product Code:	GYC
Classification Panel:	Neurology

Device Description

The INTEGRA™ Electrode Tunneling Needle is a single use device intended to be used for externalizing the leads of the Integra Cortical Electrodes away from the craniotomy site for patients undergoing brain mapping procedures. The INTEGRA™ Electrode Tunneling Needle creates a passage under the scalp through which the electrode leads can pass to a separate exit site without contaminating the lead contacts with patient fluids. The device consists of a stainless steel trocar with a plastic tunneling sheath attached to contain the leads during passage.

Indications for Use:

The INTEGRA™ Electrode Tunneling Needle aids in externalizing the leads of the Integra Cortical Electrodes to avoid contamination with patient fluids.

Substantial Equivalence:

The proposed INTEGRA™ Electrode Tunneling Needle is identical to the existing Integra's stainless steel trocar with scalp tunneling sheath that was reviewed by the FDA as part of K904883, OPTYX Intracranial Fiberoptic Pressure Monitoring Device, cleared to market on July 24, 1991. There are no changes to the material or design.

The proposed INTEGRA™ Electrode Tunneling Needle is to be used with Integra Cortical Electrodes, cleared to market under 510(k) K926424 and K082250.

Performance Testing and Testing Results:

The testing verified that the functional Design Outputs are consistent with the Design Input requirements for the INTEGRA™ Electrode Tunneling Needle. Functional testing ensured all the samples had the leads well contained within the plastic tunneling sheath during tunneling with no evidence of contamination/contact with animal tissue. Testing was completed to check the resistance of the electrode before and after tunneling to ensure that the tunneling device did not adversely affect the electrode. All the test results were found to be in accordance with the passing criteria dictated in the Design Verification Protocol and the Product Specification.

Conclusion:

Based on the predicate information and the performance testing summarized above, the device is as safe and effective as the legally marketed predicate device identified in the Substantial Equivalence section above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
c/o Mr. Derek Cao
Regulatory, Quality, Clinical Affairs Associate
311 Enterprise Drive
Plainsboro, NJ 08536

NOV 2 3 2010

Re: K102802
Trade/Device Name: Integra Electrode Tunneling Needle
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: September 24, 2010
Received: September 27, 2010

Dear Mr. Cao:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102802

Indication for Use Statement

NOV 2 3 2010

510(k) Number (if known): K102802

Device Name: INTEGRA™ Electrode Tunneling Needle

Indications for Use:

The INTEGRA™ Electrode Tunneling Needle aids in externalizing the leads of the Integra Cortical Electrodes to avoid contamination with patient fluids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102802