Division of Health Technology V B (DCCFGB)
Office of Health Technology VI (DCCFH)
Division of Health Technology VI A (DCCFHA)
Division of Health Technology VI B (DCCFHB)
Division of Health Technology VI C (DCCFHC)
Office of Health Technology VII (DCCFI)
Division of Chemistry and Toxicology (DCCFIA)
Division of Immunology and Hematology (DCCFIB)
Division of Microbiology (DCCFIC)
Division of Program Management and Operations (DCCFIE)
Division of Molecular Genetics and Pathology (DCCFIG)
Office of Health Technology VIII (DCCFJ)
Division of Health Technology VIII A (DCCFJA)
Division of Health Technology VIII B (DCCFJB)
Division of Health Technology VIII C (DCCFJC)

DCFF. Organization. The Center for tobacco Product's Office of Compliance and Enforcement is headed by the Director, Office of Compliance and Enforcement and includes the following:

Division of Enforcement and Manufacturing (DCFFA)
Division of Promotion, Advertising, and Labeling (DCFFB)
Division of State Programs (DCFFC)
Division of Business Operations (DCFFD)
Division of External Programs and Resource Management (DCFFE)
Division of Product Compliance (DCFFF)

DCFD. Organization. The Center for tobacco Product's Office of Science is headed by the Director, Office of Science and includes the following:

Division of Regulatory Project Management (DCFDA)
Division of Regulatory Science Informatics (DCFDB)
Division of Product Science (DCFDC)
Division of Individual Health Science (DCFDD)
Division of Population Health Science (DCFDE)
Division of Non-Clinical Sciences (DCFDF)
Division of Research and Knowledge Integration (DCFDG)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: October 22, 2021.

Andrea Palm,

Deputy Secretary of Health and Human Services.

[FR Doc. 2021–28386 Filed 12–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1243]

Prospective Grant of an Exclusive Patent License: A Diagnostic Tool Based Upon Magnetic Resonance Spectroscopy Pre-Processing and Renormalization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the U.S. Patent listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Voxel Systems, LLC located in Houston, Texas.

DATES: Only written comments and/or applications for a license that are received by FDA's Technology Transfer Office on or before January 18, 2022, will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Ken Millburne, Food and Drug Administration Technology Transfer Office, Bldg. 1, Rm. 4213, Silver Spring, MD 20993, 240–478–1662; email: *Kenneth.Millburne@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

FDA Reference No.: E–2009–011/US–04: ''System for Magnetic Resonance Spectroscopy of Brain Tissue for Pattern-Based Diagnostics''

I. U.S. Non-Provisional Application 13/509,539, filed November 12, 2010 (FDA Reference No.: E–2009–011/US–04).

II. U.S. Patent granted November 4, 2014: U.S. Patent 8,880,354 B2 (FDA Reference No. E–2009–011/US–04).

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to: (1) Any and all in vivo use, application, or developmental activity related to the software, processing algorithm, and Licensed Processes and Products; (2) all human and animal diagnostics, in pre-clinical, or clinical utilizations for any and all maladies; (3) all human research applications for expanded magnetic resonance imaging (MRI) utilization, application development, drug development tools, molecular compound characterization, algorithms, and biomarker identification and development; and (4) all animal or other research applications and translational studies for ultra high-field MRI investigations, drug development, metabolite, and biomarker identification.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless, within 15 days from the date of this published notice, FDA receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated December 27, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28397 Filed 12–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0008]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC or Committee) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by February 2, 2022 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by February 2, 2022.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993, 301–796–5960, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to the panels listed in the table in this document.

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

Panels	Function
Circulatory System Devices Panel	Reviews and evaluate data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory and vascular systems and makes appropriate recommendations to the Commissioner of Food and Drugs.
Obstetrics and Gynecology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in obstetrics and gynecology and makes appropriate recommendations to the Commissioner of Food and Drugs.
Radiological Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational diagnostic or therapeutic radiological and nuclear medicine devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer