November 14, 2023

BrainSpec, Inc
% Carolyn Guthrie
Principal
Helix Medical, LLC
711 SE 5th Ave
Pompano Beach, Florida 33060

Re: K230856
Trade/Device Name: BrainSpec Core™ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, LNI
Dated: October 23, 2023
Received: October 24, 2023

Dear Carolyn Guthrie:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230856

Device Name
BrainSpec Core™ Software

Indications for Use *(Describe)*
BrainSpec Core™ software is a post-processing application to analyze and evaluate MR (magnetic resonance) spectroscopy data. It provides evaluation of MR Single Voxel Spectroscopy (SVS) data and MR Chemical Shift Imaging (CSI) data to support the diagnostic process. BrainSpec Core™ software includes the possibility of an integrated reading of MR images and spectroscopy data for spectroscopy exams and focuses on ease-of-use by reducing complexity.

A fit algorithm reduces the need for manual data processing and offers the user reproducible evaluation results. When interpreted by a trained physician, these results provide information that may assist in diagnosis.

The post-processing fits and displays spectra and provides intuitive representations of the metabolic profile. The calculation and display of pre-defined results such as spectra, spectral maps, and metabolite images is provided. Interactive reading of spectroscopy exams is supported by side-by-side display of MR images and spectroscopy results, and synchronized display.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K230856

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

Date of Preparation:

November 9, 2023

Applicant

BrainSpec, Inc
111 Speen St,
Framingham, MA 01701

Official Correspondent

Carolyn Guthrie
Email: cguthrie@helixmedical.us
Helix Medical LLC
704-737-2866

Device Name

Trade Name: BrainSpec Core™ Software
Common Name: Picture archiving and communications system
Regulation Description: System, Image Processing, Radiological
Regulation Number: 21 CFR 892.2050
Product Code: LLZ, LNI
Classification: Class II
Panel: Radiology

Predicate Devices

BrainSpec Core™ Software is substantially equivalent to the predicate device shown in Table 1.

Trade Name	Clearance	Claim of Equivalence for:	510(k) holder
Siemens Syngo	K120315	Primary Predicate	Siemens

Table 1: Predicate devices

Indications for Use:

BrainSpec Core™ software is a post-processing application to analyze and evaluate MR (magnetic resonance) spectroscopy data. It provides evaluation of MR Single Voxel Spectroscopy (SVS) data and MR Chemical Shift Imaging (CSI) data to support the diagnostic process. BrainSpec Core™ software includes the possibility of an integrated reading of MR images and spectroscopy data for spectroscopy exams and focuses on ease-of-use by reducing complexity.

A fit algorithm reduces the need for manual data processing and offers the user reproducible evaluation results. When interpreted by a trained physician, these results provide information that may assist in diagnosis.

The post-processing fits and displays spectra and provides intuitive representations of the metabolic profile. The calculation and display of pre-defined results such as spectra, spectral maps, and metabolite images is provided. Interactive reading of spectroscopy exams is supported by side-by-side display of MR images and spectroscopy results, and synchronized display.

Device Description

The BrainSpec Core™ Software provides analysis of magnetic resonance spectroscopy (MRS) data. MRS is a technology available on standard MRI scanners that detects the presence of various chemical compounds in a volume of tissue. The software provides these analyses:

- Estimation of the concentrations of various metabolites present in the acquired data, presented to the user as ratios concentration estimations (when water reference files is available). These metabolites include N-acetylaspartate (NAA), choline (Cho), creatine (Cr), myoinositol (mIns), and glutamine/glutamate (Glx), DL-lactic acid (Lac), and 2-hydroxygluturate (2HG-ng) expressed as a ratio.
- Spatial registration of the acquired volume with anatomical MR images, such that the spectroscopy volume is overlaid on an anatomical image in the same plane.

- Visual display of the data's spectrum (a representation of the data in which peaks correspond to specific compounds)
- Ratio measurements of each metabolite may be compared to reference percentile data if a reference interval has been established.

BrainSpec Core™ Software supports 3.0 Tesla scanners manufactured by Philips, Siemens, and GE with predefined pulse sequences: PRESS short echo (TE=25-45ms), PRESS (long echo (TE=135-144) and PRESS optimized for 2HG (TE=97).

The software provides a user interface over the web. The user must access the software via the Google Chrome web browser on any operating system, provided the computer has a reliable internet connection. The uploaded data are processed with several applications. Both the web application and the data processing software read and write files and data in Google Cloud Platform resources.

The reference intervals specific for adults indicating how user-uploaded data compares to a range of typical values for a given metabolite ratio are aggregated from decades of data from adult reference subjects with no known history of neurological or major psychiatric disorders. The reference intervals are specific to the acquisition parameters and indicated adult brain region of the uploaded data, and were determined from research studies employing those matching parameters and brain regions. Reference intervals are only displayed when the relevant acquisition parameters are matched.

Substantial Equivalence

1.1 Comparison of Intended Use

The intended use of BrainSpec Core™ Software is identical to the predicate device.

1.2 Comparison of Operating Principle

Features	**BrainSpec Core™ Software**	**syngo.MR Spectroscopy**
	Subject Device	**Predicate Device**
Quantification of spectra (i.e., determination of the intensity of metabolite signals)	Results are based on a sequence of post-processing steps; the main step is a fit of a metabolite model to the measured data	Results are based on a sequence of post-processing steps; the main step is a fit of a metabolite model to the measured data
	Baseline and phase correction automatically applied during metabolite quantification	No extra step for baseline and phase correction needed

Features	BrainSpec Core™ Software	syngo.MR Spectroscopy
	Subject Device	**Predicate Device**
	Usage of extended prior knowledge for the metabolite model (metabolites are represented by their model signals, i.e., their complete spectral pattern)	Usage of extended prior knowledge for the metabolite model (metabolites are represented by their model signals, i.e., their complete spectral pattern)
	Spectral quality check performed, with additional metrics for data quality and metabolite fits	Spectral quality check performed
Handling of spectroscopy results	Support of spectra, result tables, metabolite images, spectral maps, and image co-registration	Support of spectra, result tables, metabolite images, spectral maps, and reference images
	Interactive modification of display characteristics of spectro results (e.g., toggle fit and baseline display, add or remove metabolite ratios, and transparency for a metabolite image)	Interactive modification of display characteristics of spectro results (e.g., adjusting the range and scale for a spectrum, adjusting the range and transparency for a metabolite image)
	Interactive voxel selection on metabolite map and co-registration images with automatic update of spectrum display	Interactive voxel selection on metabolite- and reference images with automatic update of spectrum display
	Interactive voxel selection on metabolite map and co-registration images with automatic update of spectrum display	Synchronized scrolling through reference and metabolite images with automatic update of spectrum display
	Display of measurement parameters	Display of measurement parameters
	Display of measurement parameters as image test	Display of measurement parameters as image test

Features	BrainSpec Core™ Software	syngo.MR Spectroscopy
	Subject Device	**Predicate Device**
	Saving of spectro results in a PDF report for off-line viewing	Saving of spectro results as screenshots and their usage for printing
	Image co-registration available	Usage of reference images of arbitrary orientations with respect to the CSI slab possible (MPR creation for reference images)
	Visualization of default spectra	Visualization of default spectra
Usage of post processing protocols for spectroscopy	All relevant parameters for post-processing and display contained	All relevant parameters for post-processing and display contained
	Dedicated protocols for typical measurement scenarios	Dedicated protocols for typical measurement scenarios
	Automatic protocol selection	Automatic protocol selection
Usage of standardized enhanced DICOM format "MR spectroscopy object" for spectro raw data	Yes	Yes
Hardware prerequisites	Software only device	Software only device

1.3 Comparison of Technological Characteristics with the Predicate Device

Feature	Subject Device	syngo.MR Spectroscopy	Discussion of differences
Quantification of spectra (i.e., determination of the intensity	Quantification of the following metabolites: NAA, Ins, Cho,	Quantification of the following metabolites:	2HG is a metabolite quantified by the subject device but not by the predicate.

Feature	Subject Device	syngo.MR Spectroscopy	Discussion of differences
of metabolite signals)	Cr, Glx, Lac, 2HG	NAA, Ins, Cho, Cr, Glx, Lac	It is quantified in the same manner (algorithm) as the other metabolites but with different acquisition parameters.
	Values of metabolite peaks are calculated based on a linear combination	Integral values of metabolite peaks are calculated based on the fit results	The linear combination model approach to metabolite quantification improves on peak integration methods by incorporating prior knowledge of the metabolite peaks for a given pulse sequence and echo time. It allows for modeling of baseline and macromolecule contributions, which otherwise create artifacts in the spectrum that cannot be easily accounted for using peak integration. Both methods of quantification result in metabolite values / rations.
Handling of spectroscopy results	Display of quantification within a reference interval for a metabolite within a brain region, if available	Comparison of spectro results of different measurements of one and more patients	Use of reference intervals in the BrainSpec Core™ software does not alter the quantification of the metabolite. The intervals were established according to CLSI guidelines and are intended to provide further support in the diagnostic process.
	Feature not included	3D scaling of metabolite images and spectral maps	3D scaling in the predicate allows for an alternative view of the imaging and spectra. This does not alter the method for quantification and therefore does not impact the intended use of the device.
	Feature not included	Real-time spectrum update (real time updates of the spectrum without mouse clicking)	Data is processed in the BrainSpec Core™ software after spectra are acquired. Lack of an “on the fly” update does not introduce any questions of safety or effectiveness.

Feature	Subject Device	syngo.MR Spectroscopy	Discussion of differences
		("on-the-fly" display)	
Usage of post processing protocols for spectroscopy	Feature not included	User-configurable protocols	Only preset acquisition protocols are supported to limit the conditions to the tested environment.
Software prerequisites	Google Chrome version v79 or higher	Windows XP or Windows Vista	Use of a cloud-based service introduces cybersecurity concerns vs a non-wired software. Cybersecurity controls are in place to reduce the risk associated with cybersecurity.
RIS Communication	Feature not included	Yes	Reporting output does not relate to safety or performance, and is therefore considered an acceptable difference

Performance Data

The following information is provided in support of substantial equivalence.

- Valid clinical association
- Risk Management activities
- Software testing, including unit testing, and verification testing
- Off-the-Shelf software analysis
- Cybersecurity assessment

11 Conclusion

BrainSpec Core™ Software and the predicate device Siemens Syngo (K120315) have the same intended use and are available by prescription only. Any technical differences identified do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, intended use and performance data, it can be concluded that BrainSpec Core™ Software is substantially equivalent to the Siemens Syngo device.