September 14. 2021

Magstim Company Ltd.
Tom Campbell
Chief Quality and Regulatory Affairs Officer and UK Site Director
Spring Gardens
Whitland, Carmarthenshire SA34 0HR
United Kingdom

Re: K211389
Trade/Device Name: Magstim Horizon 3.0 TMS Therapy System, Horizon 3.0 System, Horizon 3.0, Horizon 3.0 with Navigation
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: May 5, 2021
Received: May 5, 2021

Dear Tom Campbell:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number K211389

Device Name
Horizon® 3.0 TMS Therapy System

Indications for Use *(Describe)*

Horizon® 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

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)

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K211389
Traditional 510(k) SUMMARY
Magstim's Horizon® 3.0 TMS Therapy System

Prepared according to the requirements outlined in 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Magstim® Company Limited
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Contact Person: Tom Campbell, Chief Quality & Regulatory Affairs Officer and UK Site Director

Date Prepared: September 14, 2021

Trade Name of Device

Horizon® 3.0 TMS Therapy System

Common or Usual Name

Repetitive Transcranial Magnetic Stimulation (rTMS) System

Classification

Repetitive Transcranial Magnetic Stimulation (rTMS) System

21 C.F.R. § 882.5805, Class II, product code OBP

Predicate Devices

K182853 Horizon® TMS Therapy System, The Magstim® Company Limited *(Primary Predicate Device)*, 21 C.F.R § 882.5805, OBP
K183376 Horizon® TMS Therapy System with Navigation, The Magstim® Company Limited *(Secondary Predicate Device)*, 21 C.F.R § 882.5805, OBP
K201158 NeuroStar Advanced Therapy, Neuronetics Inc. *(Reference Predicate Device)*, 21 C.F.R § 882.5805, OBP

Device Description

The Horizon® 3.0 TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation. ("TMS")

The Horizon® 3.0 TMS Therapy System is a non-invasive tool for the stimulation of cortical neurons for the treatment of Major Depressive Disorder in adult patients who have failed to

achieve satisfactory improvement from antidepressant medication in the current episode. The Horizon® 3.0 TMS Therapy System is used for patient treatment by prescription only under the supervision of a licensed physician. It can be used in both inpatient and outpatient settings, including physicians' offices, clinics, and hospitals.

Horizon® 3.0 TMS Therapy System is an integrated system consisting of a combination of hardware, software, and accessories. Its technological characteristics are described in further detail below.

Intended Use

Horizon® 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

Technological Characteristics

Horizon® 3.0 TMS Therapy System is offered in two system configurations: Horizon® 3.0 and Horizon® 3.0 with StimGuide+. These system configurations are comprised of the following physical components:

Horizon® 3.0	Horizon® 3.0 with StimGuide+
1. Horizon® 3.0 Stimulator a. Horizon® 3.0 Mainframe; b. Horizon® 3.0 PSU (Power Supply Unit); c. Horizon® 3.0 Interface Unit; d. Horizon® 3.0 User Interface. 2. Horizon® 3.0 Coil for MT Determination a. Horizon® MT Coil; 3. Horizon® 3.0 Coil for Treatment a. Horizon® 3.0 E-z Cool Coil. 4. Horizon® 3.0 Cart and Coil Holder a. Horizon® 3.0 E-z Cart; b. Horizon® 3.0 Coil Holder. 5. Horizon® 3.0 Camera Stand 6. Accessories a. Horizon® 3.0 Accessory Kit.	1. Horizon® 3.0 Stimulator a. Horizon® 3.0 Mainframe; b. Horizon® 3.0 PSU (Power Supply Unit); c. Horizon® 3.0 Interface Unit (Nav); d. Horizon® 3.0 User Interface; e. StimGuide+ User Interface. 2. Horizon® 3.0 Coil for MT Determination a. Horizon® MT Coil. 3. Horizon® 3.0 Coil for Treatment a. Horizon® E-z Cool Coil (Nav). 4. Horizon® 3.0 Cart and Coil Holder a. Horizon® 3.0 E-z Cart; b. Horizon® 3.0 Coil Holder. 5. Horizon® 3.0 Camera Stand 6. Accessories a. Horizon® 3.0 Accessory Kit; b. StimGuide+ Accessory Kit.

The technological differences between Horizon® 3.0 TMS Therapy System and its primary and secondary predicate devices (K182853 & K183376) includes:

- An upgraded mainframe to address component obsolescence including component upgrades to improve reliability, whilst also enabling remote upgradeability.
- A minor design change to the Power Supply Unit to facilitate the introduction of the Horizon® 3.0 Interface Unit.

- The introduction of the Horizon® 3.0 Interface Unit that runs the graphical user interface (Horizon® and StimGuide+), houses the StimGuide+ accessories for full system integration, whilst also enabling wireless network connectivity.
- Improved touch panels and graphical user interface to improve the user experience.
- An upgraded cart and arm to refine and improve the user experience for coil positioning for treatment.
- An update to StimGuide to allow users to place additional helper landmarks at any position on the patient's head. StimGuide+ can display distances to the selected landmarks.

Horizon® 3.0 TMS Therapy System also enables patients to be treated in multi-site clinics through its integration with a Patient Data Management (PDM) system, Magstim Connect. Integration of Horizon® 3.0 and Magstim Connect includes the following three functions:

1. Authentication Service
2. Synchronization Service
3. Remote Update Service

Software documentation for a "moderate" level of concern has been provided.

Non-Clinical Testing

Non-clinical testing was conducted to validate the performance of the Horizon® 3.0 TMS Therapy System and to ensure that the device performs as intended and meets the design specifications, consistent with FDA's guidance "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS).

Electrical safety and electromagnetic compatibility ("EMC") testing were conducted on the Horizon® 3.0 TMS Therapy System to demonstrate that the device is compliant with IEC 60601-1 (Ed. 3.1.) and IEC 60601-1-2 (Ed. 4.). Environmental testing and acoustic output measurements has been conducted during IEC 60601-1 (Ed. 3.1) testing to demonstrate safety and performance.

Biocompatibility evaluation has demonstrated that patient-contacting components of Horizon® 3.0 TMS Therapy System meet the requirements of ISO 10993-1 (Ed. 4.) standards. In addition, acoustic output measurements have been conducted during IEC 60601-1 (Ed. 3.1) testing to demonstrate safety and performance.

A summary of the non-clinical testing performed on the Horizon® 3.0 TMS Therapy System is provided in **Table 1**.

Table 1: Summary of Non-Clinical Testing

Test	Method	Results/ Comment
Electrical Safety Mechanical Safety	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012– Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; FDA Recognition Number: 19-4	A sample Horizon® 3.0 TMS Therapy System (specifically Horizon® 3.0 with StimGuide+) has been tested and found to be compliant to the requirements of ANSI/AAMI ES 60601-1 by independent test laboratory BSI Appliances, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
Electromagnetic Compatibility	IEC 60601-1-2: 2014 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests; FDA recognition number: 19-8	A sample of the Horizon® 3.0 TMS Therapy System (specifically Horizon® 3.0 with StimGuide+) has been tested and found to be compliant to the requirements of IEC 60601-1-2 by independent test laboratory Eurofins Hursley, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
Alarm Systems	IEC 60601-1-8 – Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems; FDA Recognition Number: 5-76	A sample Horizon® 3.0 TMS Therapy System has been tested and found to be compliant to the requirements of IEC 60601-1-8 by independent test laboratory BSI Appliances, thus demonstrating the Horizon® 3.0 TMS Therapy System is substantially equivalent to the legally marketed predicate device.
Biocompatibility	ISO 10993-1:2009 - Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; FDA Recognition Number: 2-245	Patient-contacting components of the Horizon® 3.0 TMS Therapy System include: • Enclosure of the Horizon® MT Coil; • Enclosure of the Horizon® E-z Cool Coil 3.0; • Enclosure of Horizon® E-z Cool Coil (Nav) 3.0,

	ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization; FDA Recognition Number: 2-174	All these have limited contact duration with skin (surface contacting, less than 24-hour duration). Samples of these materials have been tested and found to be compliant to the requirements of ISO 10993-1, ISO 10993-5 and ISO 10993-10 by an independent test laboratory, thus demonstrating the Horizon® TMS Therapy System is substantially equivalent to the legally marketed predicate devices.
Human Factors Testing	AAMI/ANSI HE75 - Human Factors Engineering – Design of Medical Devices; FDA Recognition Number: 5-57	Usability testing was performed to Horizon® 3.0 TMS Therapy System. The Human Factors Engineering report verifies the Horizon® 3.0 TMS Therapy System, to be safe and effective for the intended users, uses, and use environments thus demonstrating the Horizon® 3.0 TMS Therapy System is substantially equivalent to the legally marketed predicate devices.
	IEC 62366-1 - Medical Devices - Part 1: Application of Usability Engineering To Medical Devices; FDA Recognition Number: 5-114	

The Software lifecycle process, which includes verification and validation testing assures that the software performs as intended and in accordance with specifications. The potential risks of Horizon 3.0 have been identified and evaluated in compliance with ISO 14971 (Ed 2.0), and the risks were determined to be acceptable, or have been addressed with risk control measures. In addition to ISO 14971, *AAMI TIR57:2016/(R)2019 – Principles for Medical Device Security – Risk Management* was also applied to evaluate and control cyber security risks associated with the Horizon 3.0 device and the risks were determined to be acceptable.

Substantial Equivalence Discussion

The Horizon® 3.0 TMS Therapy System is substantially equivalent to the primary and secondary predicate devices, the Horizon® TMS Therapy System (K182853) and the Horizon® TMS Therapy System with Navigation (K183376).

The intended use and indications for use of the Horizon® 3.0 TMS Therapy System and the primary and secondary predicate devices is identical: all devices are intended to treat Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

The basic design of Horizon® 3.0 TMS Therapy System is substantially equivalent to the design of the predicate devices (K182853 and K183376), as all systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. All systems use the same mechanism of action, i.e., an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex.

The coil head geometry of the Horizon® 3.0 E-z Cool Coil and Horizon® 3.0 E-z Cool Coil (Nav) are identical to the predicate devices, the Horizon® E-z Cool Coil and Horizon® E-z Cool Coil (SG), cleared under K182853 and K183376. For this reason, the magnetic field characteristics of the system are identical to the predicate devices, therefore equivalent safety and performance is assured. Consequently, no additional testing of the magnetic field characteristics of the system is necessary to meet the requirement of FDA's guidance document "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems" in order to demonstrate safety and performance.

The remaining technological characteristics of the Horizon® 3.0 TMS Therapy System, the Horizon® TMS Therapy System (K182853) and the Horizon® TMS Therapy System with Navigation®, including mechanism of action, specifications, treatment procedure, are very similar, and in most cases, identical.

The integration of Magstim Connect that could adversely affect the device (Authentication and Synchronization) have been evaluated, controlled and validated. Magstim has concluded that these functions do not compromise the established safety and effectiveness of the device and that the benefit of introducing these networked functions to enable greater patient management, and the ability for patient information to be persisted across multiple clinics/sites, outweighs the identified risk and the risk has been controlled to an acceptable level. The ability for Horizon® to integrate with Magstim Connect is supported by the FDAs clearance of the Neurostar Advanced Therapy (K201158) which includes the integration of TrakStar (MDDS) with their NeuroStar Advanced Therapy System for patient data management.

The principles of operation of the Horizon® 3.0 TMS Therapy System is equivalent to the primary and secondary predicate devices. The methods for determining Motor Threshold both with and without EMG and determining the coil position for treatment in both navigated and non-navigated device configurations remain unchanged compared to the predicate devices. The the FDA cleared standard rTMS protocol and the FDA cleared iTBS protocol are identical to those of the predicate devices.

A summary of the similarities and minor differences between the Horizon® 3.0 TMS Therapy System and its primary and secondary predicate devices; the Horizon TMS Therapy System (K182853) and the Horizon TMS Therapy System with Navigation (K183376) are described in **Table 2.**

Conclusions

The intended use and indications for use are identical between the Horizon® 3.0 TMS Therapy System (subject of this submission) and the primary and secondary predicate devices (K182853 and K183376).

Although the technological characteristics of the Horizon® 3.0 TMS Therapy System differ slightly following the introduction of product improvements and patient data management integration, non-clinical testing demonstrates that the Horizon® 3.0 is as safe and effective compared to its primary and secondary predicate devices, the Horizon® TMS Therapy System (K182853) and the Horizon® TMS Therapy System with Navigation (K183376).

Furthermore, the principles of operation remain unchanged between the Horizon® 3.0 TMS Therapy System and its primary and secondary predicates. The labeling for both the Horizon® 3.0 TMS Therapy System and its primary and secondary predicates instruct users that the FDA cleared Standard Treatment Protocol and FDA cleared iTBS Treatment Protocol are the only stimulation parameters that have been established to be safe and effective for treating MDD in clinical trials and should be set as the default treatment parameters for treating adult patients with MDD who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

Thus, the information and data provided in this 510(k) premarket notification submission support a finding of substantial equivalence for the Horizon® 3.0 TMS Therapy System.

Table 2: Substantial Equivalence Summary

Criteria	**Horizon® 3.0 TMS Therapy System** (Subject of this submission)	**Horizon® TMS Therapy System with Navigation** (K182853) *(Primary Predicate)*	**Horizon® TMS Therapy System** *(* K183376 *(Secondary Predicate)*
Manufacturer	Magstim Company Limited	Magstim Company Limited	Magstim Company Limited
Device Name	Horizon® 3.0 TMS Therapy System	Horizon® TMS Therapy System with Navigation	Horizon® Therapy System
Clearance date		04/03/2019	03/15/2019
510(k) number	K211389	K183376	K182853
Device code	OBP	OBP	OBP
Intended Use/ Indications for Use	The Horizon® 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	The Horizon® TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	The Horizon® Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
Standard Treatment Protocol			
Magnetic Field Intensity	120% of the MT	120% of the MT	120% of the MT
Stimulus Frequency	10 Hz	10 Hz	10 Hz
Stimulus Train duration	4 sec	4 sec	4 sec
Inter-train interval	11-26 sec	11-26 sec	11-26 sec
Number of trains	75	75	75
Magnetic Pulses per Session	3000	3000	3000
Treatment Session Duration	18.8 min–37.5 min	18.8 min–37.5 min	18.8 min–37.5 min
Sessions/week	5	5	5

Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex
iTBS Treatment Protocol			
Stimulation Intensity	120% of the MT	120% of the MT	N/A
Repetition Rate	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	N/A
Train Duration	2 sec	2 sec	N/A
Inter-train Interval	8 sec	8 sec	N/A
Burst Pulses	3	3	N/A
Bursts	200	200	N/A
Inter Pulse interval	20 msec	20 msec	N/A
Number of trains	20	20	N/A
Number of Pulses per Session	600	600	N/A
Treatment Session Duration	3 minutes 9 seconds	3 minutes 9 seconds	N/A
Sessions/week	5	5	N/A
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	N/A
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	N/A

Stimulating Coils							
Coil Reference	Horizon® MT Coil	Horizon® 3.0 E-z Cool Coil	Horizon® 3.0 E-z Cool Coil (Nav)	Horizon® MT Remote Coil	Horizon® E-z Cool Coil (SG)	Horizon® MT Remote Coil	Horizon® E-z Cool Coil
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Configuration	Figure of 8	Figure of 8	Figure of 8	Figure of 8	Figure of 8	Figure of 8	Figure of 8
Core Material	Air	Air	Air	Air	Air	Air	Air
Inductance (nominal)	15µH	16.5µH	16.5µH	15µH	16.5µH	15µH	16.5µH
Pulse Width	330µs	340µs	340µs	330µs	340µs	330µs	340µs

Horizon 3.0 Specifications			
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9	0.28 - 1.9	0.28 - 1.9
Frequency range (Hz) at 100%	1 – 20	1 - 20	1 - 20
Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m	150 V/m	150 V/m
Maximum magnetic field strength (T) at coil surface	1.0T	1.0T	1.0T
Maximum magnetic field strength (T) at a depth of 2cm	0.4T	0.4T	0.4T
Maximum magnetic field gradient (dB/dt) (kT/s) at coil surface	18 kT/s	18 kT/s	18 kT/s

Coil Positioning and MT Determination Principle				
System Configuration	**Horizon® 3.0**	**Horizon® 3.0 with StimGuide+**	**Horizon® Performance**	**Horizon® Performance with StimGuide**

Coil Position Principle	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC from MT hotspot.
MT Response Detection	Visual qualitative monitoring for APB response	Option 1. EMG provides quantitative data based on which user defines MT. Option 2. Visual qualitative monitoring for APB response	Visual qualitative monitoring for APB response	Option 1. EMG provides quantitative data based on which user defines MT. Option 2. Visual qualitative monitoring for APB response