



June 5, 2025

Synapse Biomedical, Inc.  
Jason Fiest  
Vice President - Quality and Regulatory  
300 Artino Street  
Oberlin, Ohio 44074

Re: K242704  
Trade/Device Name: Synchrony (20-3000)  
Regulation Number: 21 CFR 882.5810  
Regulation Name: External Functional Neuromuscular Stimulator  
Regulatory Class: Class II  
Product Code: GZI, IPF, KQX  
Dated: May 6, 2025  
Received: May 6, 2025

Dear Jason Fiest:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lauren E. Woodard -S

for Amber Ballard, PhD  
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

## Indications for Use

510(k) Number (*if known*)  
K242704

Device Name  
Synchrony® (20-3000)

### Indications for Use (*Describe*)

The Synchrony (20-3000) is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES).

- Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES).

- Maintenance and/or increase of hand range of motion.
- Prevention and/or retardation of disuse atrophy.
- Increase in local blood circulation.
- Reduction of muscle spasm.
- Re-education of muscles.

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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**Submitter Information:**

Name: Jason Fiest

Address: 300 Artino Street, Oberlin, OH 44074

Contact person: Jason Fiest – Vice President – Quality and Regulatory

Telephone number: +1.440.774.2488 x138

Date the summary was prepared: 6/4/2025

Device Common Name: External neuromuscular stimulator

Device trade/proprietary name: Synchrony® 20-3000

Device Classification: Class 2

Product Code: GZI, IPF, and KQX

Regulation number: 882.5810 External functional neuromuscular stimulator

Predicate devices:

K123636 - NESS H200® Wireless Rehabilitation System with optional Intelli-connect

K960457- EMS-2C Med Labs Inc.

**Description of Subject Device:**

The Synchrony (20-3000) system is a functional electrical stimulation (FES) device and a powered muscle stimulator. It is specifically designed to enhance hand functionality in patients with arm paresis through a range of customizable therapies. The system integrates five major components: the Stimulator, Sensor, Patient Interface (electrodes), Motor Point Probe, and Clinician App. The therapies are directed and programmed by a clinician through an iOS based application and then the patient may apply the therapy at their home with the Stimulator and Sensor.

The Synchrony system supports three primary therapeutic modes: Contralaterally Controlled Electrical Stimulation (CCFES), cyclical Neuromuscular Electrical Stimulation (CNMES), and Functional Task Practice (FTP). The CCFES mode uses sensor data from the patient's unimpaired side to control the timing, intensity, and movement of the paretic hand/arm, synchronizing stimulation with natural motor patterns. The cyclical NMES mode delivers repetitive stimulation to targeted muscles, aiding in muscle re-training, as described in the systematic review of research studies using cyclic NMES. The FTP mode allows for direct control of hand movements during task-oriented exercises, using real-time sensor feedback and stimulator output.

Stimulation is delivered through up to four electrodes placed on identified motor points, using symmetric balanced biphasic pulses. The system offers preset stimulation amplitudes of 20mA, 40mA, and 60mA, with a pulse width adjustable between 1-250 µsec, providing high precision with 1 µsec resolution. The device's enclosure is constructed from biocompatible ABS Cycology, ensuring durability and patient safety, and is rated IP22 for ingress protection.

The stimulator can operate independently or in conjunction with the Synchrony Sensor, depending on the therapy mode selected. The Sensor, which communicates wirelessly with the Stimulator via Bluetooth Low Energy (BLE), uses a Class I laser that is compliant with 21 CFR 1040.10 and 21 CFR 1040.11 to measure hand opening and closure distances, enabling accurate therapeutic adjustments. Both the Stimulator and Sensor are wirelessly charged using an FCC Part 15 compliant charging pad, enhancing ease of use and handling.

The Synchrony system is engineered for ease of use with user-friendly control interfaces for both patients and clinicians. It incorporates a range of safety mechanisms to ensure effective and safe operation, making it a versatile and reliable tool for improving hand functionality through personalized therapeutic interventions.

**Intended Use:**

Synchrony is intended for use in adult patients (22 years and older) whose paralysis or paresis is caused by upper motor neuron injury (e.g., stroke, spinal cord injury, etc.) by prescription use only.

**Indications for Use:**

The Synchrony System is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES).

- Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES).

- Maintenance and/or increase of hand range of motion.
- Prevention and/or retardation of disuse atrophy.
- Increase in local blood circulation.
- Reduction of muscle spasm.
- Re-education of muscles.

**Substantial Equivalence:**

The Synchrony system has been compared with the predicate device: the H200 Wireless Hand Rehabilitation System with Optional Intelli-Connect Earpiece Triggering Device (K123636) by Bioness, Inc.

The Indications for Use of the Synchrony system and Bioness H200 are the same. Both, the Synchrony and H200 are battery operated stimulators. The Synchrony device has four potential output electrodes and one common return electrode. The Synchrony uses commercially available Surface electrode (Axelgaard Ultrastim Electrodes Model Numbers SN2020 and SN2040; FDA submission K130987) that can each be placed on any of the desired muscles of the hand or forearm.

Both devices use a Clinician application to program settings into the device for individual use by patients. Both devices also have a wireless input device that can be used to control the stimulation. The H200 device uses the wireless “Intelli-Connect” trigger switch to trigger a “pre-determined stimulation sequence at the H200W orthosis”. The Synchrony device uses the wireless Sensor, that is essentially an application specific hand opening goniometer, to output pre-determined stimulation at a level related to the hand opening of the unaffected hand.

Since the Synchrony device doesn’t have fixed positioning of the surface electrodes, the device includes a motor point probe for the clinician to use to locate the optimal electrode positioning for the desired muscle recruitment. This probe is a spring loaded stainless steel electrode disk that shuts off stimulation before the disk loses contact with the skin, thus avoiding a high current density stimulation as the probe is lifted from the skin location.

The EMS-2C from Med Labs Inc. is also included as a predicate device to enhance the substantial equivalence comparison for the Motor Point Probe (MPP) accessory of the Synchrony system. Like Synchrony, the EMS-2C is a powered muscular stimulator with the same product code (IPF). It was selected for its probe-shaped stimulator, which resembles the design and use of the Motor Point Probe.

Despite some minor differences in the technological variations between the Synchrony system and its predicate devices they do not raise new questions regarding safety and effectiveness. The Synchrony system complies with the IEC 60601-2-10 standard for basic safety and essential performance of nerve and muscle stimulators. The evaluation of the Synchrony system demonstrates that it is substantially equivalent to the predicate devices in terms of safety, effectiveness, and overall performance.

**Summary table of technical characteristics vs. predicate devices:**

	<b>Synchrony New Device</b>	<b>Bioness H200 Predicate</b>	<b>Med Labs EMS-2C Predicate<sup>5</sup></b>	<b>Difference / Rationale</b>
1. 510(k) Number	K242704	K123636	K960457	N/A
2. Device Name, Model	Synchrony, 20-3000	NESS H200 Wireless Hand Rehabilitation System	EMS-2C	N/A
3. Manufacturer	Synapse Biomedical Inc.	Bioness Inc.	Med Labs, Inc.	N/A
4. Classification Regulation(s)	21 CFR 882.5810	21 CFR 882.5810	21 CFR 890.5850	Same. No impact on Safety and Effectiveness
5. Product Code	GZI: External Functional Neuromuscular Stimulator IPF: Powered Muscle Stimulator KQX: Goniometer AC-Powered	GZI: External Functional Neuromuscular Stimulator IPF: Powered Muscle Stimulator	IPF: Powered Muscle Stimulator	Same. No impact on Safety and Effectiveness
6. Indications for Use:	The Synchrony System is an electrical stimulation device indicated for the following uses:  Functional Electrical Stimulation (FES). o Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.  NeuroMuscular Electrical Stimulation (NMES).	The NESS H200® Wireless System is an electrical stimulation device indicated for the following uses:  Functional Electrical Stimulation (FES). o Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.  NeuroMuscular Electrical Stimulation (NMES). o Maintenance and/or	Not Publicly Available	

	<ul style="list-style-type: none"> <li>o Maintenance and/or increase of hand range of motion.</li> <li>o Prevention and/or retardation of disuse atrophy.</li> <li>o Increase in local blood circulation.</li> <li>o Reduction of muscle spasm.</li> <li>o Re-education of muscles</li> </ul>	<ul style="list-style-type: none"> <li>increase of hand range of motion.</li> <li>o Prevention and/or retardation of disuse atrophy.</li> <li>o Increase in local blood circulation.</li> <li>o Reduction of muscle spasm.</li> <li>o Re-education of muscles</li> </ul>		
<p>7. Power Source(s)</p> <ul style="list-style-type: none"> <li>- Method of Line Current Isolation</li> <li>- Patient Leakage Current</li> <li>- Normal condition</li> <li>- Single fault condition</li> </ul>	Battery	Battery	Battery	Same. No impact on Safety and Effectiveness
7. Number of Output Modes	1	- Not Publicly Available	2 (EMS-2C has IDC (Interrupted Direct Current) and Pulse Mode)	Synchrony has one output mode, and the EMS can be toggled between two. No impact on safety or effectiveness.
<p>8. Number of Output Channels</p> <ul style="list-style-type: none"> <li>- Synchronous or Alternating</li> <li>- Method of Channel Isolation</li> </ul>	<p>1 – 4</p> <ul style="list-style-type: none"> <li>- Alternating</li> <li>- Solid state relay</li> </ul>	<ul style="list-style-type: none"> <li>- Not Publicly Available</li> <li>- Not Publicly Available</li> <li>- Not Publicly Available</li> </ul>	<ul style="list-style-type: none"> <li>- Not Publicly Available</li> <li>-Not Publicly Available</li> <li>-Not Publicly Available</li> </ul>	Synchrony has fewer output channels than the predicates. No impact on safety or effectiveness by having the same or fewer output channels.
9. Regulated Current or Voltage	Regulated Current	Not Publicly Available	Not Publicly Available	Synchrony uses Regulated Current, Same as the predicate devices. No impact on safety or effectiveness
10. Software / Firmware / Microprocessor Control	Yes	Not Publicly Available	Not Publicly Available	Same. No impact on safety or effectiveness

	<b>Synchrony New Device</b>	<b>Bioness H200 Predicate</b>	<b>Med Labs EMS-2C Predicate<sup>5</sup></b>	<b>Difference / Rationale</b>
11. Automatic Overload Trip	Yes	Not Publicly Available	Not Publicly Available	Same, Information for Predicate Devices is not publicly available
12. Automatic No-Load Trip	No	Not Publicly Available	Not Publicly Available	Same. No impact on safety or effectiveness.
13. Automatic Shut Off	Yes	Not Publicly Available	Not Publicly Available	Same. No impact on safety or effectiveness.
14. Patient Override Control	Yes	Not Publicly Available	Not Publicly Available	Same. No impact on safety or effectiveness.
15. Indicator Display - On/Off Status - Low Battery - Voltage/Current Level	Yes Yes Yes	Not Publicly Available Not Publicly Available Not Publicly Available	Not Publicly Available Not Publicly Available Not Publicly Available	Synchrony App displays same or more data as the predicate devices. No impact on safety or effectiveness.
16. Timer Range (minutes)	1-51 minutes	N/A	N/A	N/A
15. Compliance with 21 CFR 898	Yes	N/A	N/A	Same. No impact on safety or effectiveness
17. Weight	Stimulator: 2.2 Ounces  Sensor: 1.7 Ounces  Motor Point Probe: 2 Ounces	Not Publicly Available	Not Publicly Available	Same. No impact on safety or effectiveness.
18. Dimensions (in. W x H x D)	Stimulator: Diameter = 2.8 inches, Depth = 0.9 inches  Sensor: Height = 3.8 inches, Width = 1.6 inches, Depth = 3.1 inches  Motor Point Probe: Diameter = 1 inch, Length = 6 inch	Not Publicly Available	Not Publicly Available	Same. No impact on Safety and Effectiveness

	<b>Synchrony New Device</b>	<b>Bioness H200 Predicate</b>	<b>Med Labs EMS-2C Predicate<sup>5</sup></b>	<b>Difference / Rationale</b>
19. Housing Materials and Construction	Synchrony Stimulator Enclosure: Cycloy-ABS, Polycarbonate Matte (overlay) Sensor: Cycloy-ABS, Polycarbonate Matte (overlay) Motor Point Probe: Cycloy-ABS	Not Publicly Available	Not Publicly Available.	Same. No impact on Safety and Effectiveness

Notes:

<sup>1</sup>Power Source: For AC line-powered devices, specify line voltage and frequency, method of line current isolation, and measured patient leakage current; for battery powered devices, specify number, size and type of batteries.

<sup>2</sup>Leakage Current: Patient leakage current should be measured under both normal conditions and under single fault conditions and should be no greater than 100 microamperes and 500 microamperes, respectively. The method of testing should be described, e.g., IEC 60601-1.

<sup>3</sup>Output Modes: For devices with more than one output mode, the information in Section 1 and Section 3 should be completed for each output mode.

<sup>4</sup>Output Channels: For devices with more than one output channel, describe whether the outputs are delivered in a synchronous and/or alternating fashion, and describe the method of achieving channel isolation.

<sup>5</sup>The Med Labs EMS-2C predicate device is being compared to the Synchrony Motor Point Probe being used with the Synchrony Stimulator

**Output Specifications**

<b>Output Specifications</b>	<b>Synchrony New Device</b>	<b>Bioness H200 Predicate</b>	<b>Med Labs EMS-2C Predicate<sup>6</sup></b>	<b>Difference/Rationale</b>
Waveform	Balanced Biphasic	Not Publicly Available	Not Publicly Available	Same. No impact on safety and effectiveness.
Shape	Rectangular	Not Publicly Available	Not Publicly Available	Same. Synchrony uses a rectangular waveform shape, which is commonly used in surface neuromuscular stimulation. No impact on safety and effectiveness.
Maximum Output Voltage	32V @ 500Ω 96V @ 2KΩ 96V @ 10KΩ VRMS 4.4V @ 500Ω VRMS 13.1V @ 2KΩ VRMS 13.1V @ 10KΩ	Not Publicly Available	Not Publicly Available	Max output voltage at 500 Ohms, 2000 Ohms, and 10,000 Ohms is within the maximum output voltage range for the predicate devices. No impact on safety and effectiveness.
Maximum Output Current	64mA @ 500Ω 48mA @ 2KΩ 9.6mA @ 10KΩ IRMS 8.7mA @ 500Ω IRMS 6.5mA @ 2KΩ IRMS 1.3mA @ 10KΩ	Not Publicly Available	Not Publicly Available	Synchrony applied peak and RMS current are lower at nominal and maximum load compared to predicate  The maximum output current is lower for the EMS-2C device than Synchrony.  The Synchrony and predicate devices both provide effective muscle contractions over their range of current setting within the safe current density limits. The Synchrony device disperses charge to a lower density and thus utilizes higher currents but lower current density within the safe current density limits. No impact on safety and effectiveness.
Pulse Width	1 - 250 μsec	Not Publicly Available	Not Publicly Available	Synchrony pulse width is programmable in 1 usec increments, rather than pre-set selections on the predicate. No impact on safety and effectiveness.
Frequency	32-37 Hz	Not Publicly Available	Not Publicly Available	Synchrony frequency range falls within the predicate ranges  Synchrony uses a lower stimulating frequency than predicate. No impact on safety and effectiveness.
For interferential modes	N/A	N/A	N/A	N/A

Output Specifications	Synchrony New Device	Bioness H200 Predicate	Med Labs EMS-2C Predicate <sup>6</sup>	Difference/Rationale
- Beat Frequency (Hz)				
For multiphasic waveforms - Symmetrical phases - Phase Duration	-N/A -N/A	-N/A -N/A	-N/A -N/A	N/A
Net Charge ( $\mu\text{C}$ )	0 $\mu\text{C}$ @ 500 $\Omega$	Not Publicly Available	Not Publicly Available	Charged balanced biphasic waveform for Synchrony and a monophasic waveform for predicate. No impact on safety and effectiveness.
Maximum Phase Charge ( $\mu\text{C}$ ) @ 500 $\Omega$	22-1004 (2x2''): 16 $\mu\text{C}$ 22-3001 (2x4''): 16 $\mu\text{C}$ 23-3003 (MPP): 11 $\mu\text{C}$	N/A	N/A	Information unavailable for predicate devices.
Maximum Current Density ( $\text{mA}/\text{cm}^2$ ) @ 500 $\Omega$	22-1004 (2x2''): 0.34 $\text{mA}/\text{cm}^2$ 22-3001 (2x4''): 0.17 $\text{mA}/\text{cm}^2$ 23-3003 (MPP): 1.33 $\text{mA}/\text{cm}^2$	N/A	Not Publicly Available	Synchrony has a lower maximum current density at 500 $\Omega$ than EMS-2C given the larger probe tip diameter of the MPP. Both current densities comply with FDA expectations that maximum current density must be below 2 $\text{mA}/\text{cm}^2$ for stimulating electrodes under the IPF product code. No impact on safety and effectiveness.
Maximum Power Density ( $\text{W}/\text{cm}^2$ ) @ 500 $\Omega$	22-1004 (2x2''): 0.0015 $\text{W}/\text{cm}^2$ 22-3001 (2x4''): 0.0007 $\text{W}/\text{cm}^2$ 23-3003 (MPP): 0.0040 $\text{W}/\text{cm}^2$	N/A	Not Publicly Available	Product testing verified safety and effectiveness of power density.
Burst Mode a. Pulses per burst b. Bursts per second c. Burst duration (sec)	a. N/A b. N/A c. N/A	a. N/A b. N/A c. N/A	Not Publicly Available	N/A (No Burst Mode)
ON Time (usec)	0-500 $\mu\text{sec}$	Not Publicly Available	Not Publicly Available	ON time is based upon the pulse width. Synchrony has a programmable pulse width from 1-250 usec (X2) equals 500 usec. ON time is within the range of the predicate device for safety and effectiveness. No impact on safety and effectiveness.

Output Specifications	Synchrony New Device	Bioness H200 Predicate	Med Labs EMS-2C Predicate <sup>6</sup>	Difference/Rationale
OFF Time (usec)	100 μsec	Not Publicly Available	Not Publicly Available	For a single pulse the OFF time (interpulse delay) is set at 100 usec. The set 100μs interpulse delay allows for propagation of an action potential prior to reversing the depolarizing potential with the recharge phase of the pulse. No impact on safety and effectiveness.

<sup>6</sup>The Med Labs EMS-2C predicate device is being compared to the Synchrony Motor Point Probe being used with the Synchrony Stimulator

**Summary of Performance Testing:**

<b>Standard</b>	<b>Edition / Year</b>
IEC60601-1 Basic Safety & Essential Performance	2020
IEC60601-1-2 Electromagnetic Disturbances	2020
IEC60601-1-6 Usability	2020
IEC60601-1-11 Home Healthcare Environment	2020
IEC60601-2-10 Nerve and Muscle Stimulators	2016
IEC62304 Software Life Cycle Processes	2015
ISO14971 Risk Management	2019
ISO10993-1 Biological Evaluation	2018
ISO10993-5 Cytotoxicity	2009
ISO10993-10 Sensitization	2021
ISO10993-23 Irritation	2021
IEC60825-1 Safety of Laser Products	2014
IEC62366-1 Usability	2020
IEC 62133-2 Battery testing, Lithium systems	2021
ASTM D4169 Shipping Containers and System	2022
ANSI-AAMI ST98 Cleaning Process	2022
ANSI C63.27 Wireless Coexistence	2017
47 CFR Part 15 Subpart B RF Devices	2023
AAMI TIR57 Cybersecurity Risk Mgt	2019+(R2023)
AAMI TIR97 Cybersecurity Post Market Risk Mgt	2019+(R2023)
ASTM F899-20 Standard Specification for Wrought Stainless Steels for Surgical Instruments	2023

**Clinical data:** No clinical data were reviewed in this submission in support of the subject device.

**Conclusions:**

Based upon the comparisons with predicate devices and performance testing conducted, we believe the Synchrony device to be substantially equivalent and safe and effective for its intended use.