K123795

510(k) Summary

JUN 0 3 2014

1 Submitter Information

Manufacturer:	Otto Bock Healthcare Product GmbH
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Date Prepared:	October 8, 2012
Date Revised:	May 30, 2014

2 Device Information

Trade Name:	Axon-Bus Prosthetic System
Common or Usual Name:	Powered, External Upper Limb Prosthetic System
Classification Name:	Cutaneous Electrode (21 CFR 882.1320)
Classification Product Code:	GXY (Electrode, Cutaneous)
Subsequent Product Code:	IQZ (Hand, External Limb Component, Powered)

3 Identification of Legally Marketed Predicate Devices

Name:	MyoSystem with Customizing
Manufacturer:	Otto Bock HealthCare Products GmbH
510k Number:	K032833
Date Cleared:	June 3rd, 2010

Name:	i-limb System
Manufacturer:	Touch Bionics, Inc.
510k Number:	-
Date Cleared:	-

Name:	Pro Hand System
Manufacturer:	Motion Control, Inc
510k Number:	-
Date Cleared:	-

Name:	Bebionic System
Manufacturer:	RSL Steeper
510k Number:	-
Date Cleared:	-

4 Description of the Device

4.1 General Description

The Axon-Bus Prosthetic System is to be used exclusively for upper limb exoprosthetic fitting. The Axon-Bus Prosthetic System is suitable for unilateral or bilateral amputations starting with the transradial/transhumeral amputation level or, in case of dysmelia, for forearm or upper arm fittings.

The Axon-Bus prosthetic system was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill, mountain biking) or extreme sports (free climbing, paragliding, etc.). Furthermore, the Axon-Bus prosthethic system should not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment. The prosthesis is intended exclusively for use on one patient. Use of the product by another person is not approved by the manufacturer. Fitting a patient with the Axon-Bus prosthetic system may only be carried out by a prosthetist who has been authorized by Ottobock after completion of a corresponding training course.

System Components:

- Michelangelo Hand (terminal device)
- AxonFlexion Adapter (passive flexion)
- AxonRotation Adapter (passive rotation)
- AxonArm (passive elbow joint with mechanical and/or electrical lock)
- AxonEnergy Integral (battery)
- AxonCharge (charger)
- AxonMaster (control unit)
- Electrode (detecting EMG Input signals)
- AxonSoft (adjustment software)
- AxonSkin (prosthetic glove)

4.2 Device Functions

The components of the Axon-Bus Prosthetic System are assembled by a prosthetist according to the individual needs of the amputee.

Adjustments to the prosthesis components can be performed through Bluetooth® data transfer using the AxonSoft software. The Bluetooth module is integrated into the control unit. The program is selected for the respective user situation from among four control option.

The adjustment software running on a personal computer allows the prosthetist to adjust the settings of the system by selecting the right program from among four control option.

The hand component contains two drives. The main drive of the hand component is responsible for the gripping movements and gripping force. Actively driven elements are the thumb, index finger and middle finger while the ring finger and little finger passively follow the other fingers. The thumb drive permits electronic positioning. Rotating the thumb outward creates a wide open palm, so that additional movement options are possible.

Flexion and extension (bending and stretching) are based on the relaxed wrist (flexible mode). Pronation and supination (inward and outward rotation) can be passively performed by the user.

The elbow component allows passive flexion and extension. Locking and unlocking is carried out mechanically (e.g., by means of body harnesses) or electrically (e.g., by means of electrode).

4.3 Description and Comparison of the Control Options

Control Option 1 – "2-Multi"			
Feature	**OPEN**	**CLOSE**	**Indication**
Channel	Input signal no. 2	Input signal no. 1	For patients with 2 (strong) electrode signals The neutral position of the Michelangelo Hand is the initial position for Opposition Mode and Lateral Mode.
Needed signals	Sustained electrode signal	Sustained electrode signal.	
Application of gripping force	N.A. (no gripping force applied during opening of the hand)	Proportional, according to strength of the electrode signal (resulting from the muscle contraction).	
Application of gripping speed	Proportional, according to strength of the electrode signal (resulting from the muscle contraction).		
Stopping	No electrode signal		

Comparison of this control option with the predicate devices:
No differences (all predicate devices and the Axon-Bus Prosthetic System (2-Multi) are controlled proportional (gripping force and gripping speed) with 2 electrodes.

Control Option 2 – "2-ELE"			
Feature	**OPEN**	**CLOSE**	**Indication**
Channel	Input 2	Input 1	For patients with 2 (weak) electrode signals. The open position of the Michelangelo Hand is the initial position for Lateral Mode, Opposition Mode and Neutral Mode.
Needed signals	Sustained electrode signal	Sustained electrode signal.	
Application of gripping force	N.A. (no gripping force applied during opening of the hand)	Proportional, according to strength of the electrode signal (resulting from the muscle contraction).	
Application of gripping speed	Proportional, according to strength of the electrode signal (resulting from the muscle contraction). Range of proportionality can be adjusted.		
Stopping	No electrode signal		

Comparison of this control option with the predicate devices:
Both, Pro Hand System and the Axon-Bus Prosthetic System (2-ELE) can be controlled with reduced proportionality (gripping force and gripping speed) with 2 electrodes. The MyoSystem with Customizing offers reduced proportionality for only 1 electrode. No detailed information about other predicate devices.

Establishing digital control option (using and adjustment of "2-ELE")			
Feature	**OPEN**	**CLOSE**	**Indication**
Channel	Input 2	Input 1	For patients with 2 very weak electrode signals. Adjust working range according to the weak electrode signals -> if selected threshold is reached, constant gripping force and constant gripping speed are applied (digital behavior). The open position of the Michelangelo Hand is the initial position for Lateral Mode, Opposition Mode and Neutral Mode.
Needed signals	Sustained electrode signal	Sustained electrode signal.	
Application of gripping force	N.A. (no gripping force applied during opening of the hand)	Time proportional: The level of the gripping force is determined by the duration of the electrode signal	
Application of gripping speed	constant speed by means of a muscle signal at any level exceeding the adjusted threshold	constant speed by means of a muscle signal at any level exceeding the adjusted threshold	
Stopping	No electrode signal		

Comparison of this control option with the predicate devices:
Both, MyoSystem with Customizing and the Axon-Bus Prosthetic System (using and adjustment of control option "2-ELE") are controlled with constant speed and time proportional gripping force with 2 electrodes. No detailed information about other predicate devices.

Control Option 3 – "1-Vario"			
Feature	**OPEN**	**CLOSE**	**Indication**
Channel	Input 1		For patients with 1 (strong) electrode signal The open position of the Michelangelo Hand is the initial position for Lateral Mode, Opposition Mode and Neutral Mode.
Needed signals	Increasing signal through muscle contraction	Declining signal through muscle relaxation	
Application of gripping force	N.A. (no gripping force applied during opening of the hand)	Proportional to the decline of the electrode signal	
Application of gripping speed	Proportional: The speed is determined by the speed and strength of the muscle contraction/relaxation.		
Stopping	Through very slow muscle relaxation via the electrode.		

Comparison of this control option with the predicate devices:
Pro Hand System, MyoSystem with Customizing and the Axon-Bus Prosthetic System (1-Vario) are controlled with increasing/declining signals with 1 electrode. No detailed information about other predicate devices.

Control Option 4 – "1-Double"			
Feature	**OPEN**	**CLOSE**	**Indication**
Channel	Input 1		For patients with 1 strong electrode signal The open position of the Michelangelo Hand is the initial position for Lateral Mode, Opposition Mode and Neutral Mode.
Needed signals	with a fast and strong signal	with a slow, gentle signal	
Application of gripping force	N.A. (no gripping force applied during opening of the hand)	determined by the duration of the electrode signal	
Application of gripping speed	Constant		
Stopping	No electrode signal		

Comparison of this control option with the predicate devices:
Pro Hand System, MyoSystem with Customizing and the Axon-Bus Prosthetic System (1-Double) are controlled with time proportional gripping force and constant gripping speed with 1 electrode. A high or strong muscle signal opens the hand, and a low signal closes the hand. No detailed information about other predicate devices.

4.4 Description and Comparison of Switching Methodes

The AxonMaster offers five switching methodes. The prosthetist selects the switching methodes according to the user needs. The switching events are triggered by muscle signals of the user. As a result of a triggered switching event the user can switch between different joints and gripping patterns.

Method / Description	Co-Contraction	Four-Channel Control	Pulse	Long Open	Automatic Switching after Neutral Position is Reached
Required signals	2	2	1	1	0 (no signal required, switching after neutral position is reached)
Indication	For patients with co-contraction ability	For patients with 2 fast HI signals	For patients with one HI signal	For patients who can maintain the open hand position with a high signal.	For patients who have a preferred type of grip
Execution	Both electrode signals must exceed the co-contraction thresholds within a certain time, and then decline.	Quick and strong signals from either electrode controls one joint or gripping pattern. Slow and weak signals from either electrode controls another joint.	The electrode signal must exceed the pulse threshold and then decline.	The electrode signal for opening must be held at the value for the maximum speed for a certain period of time when the hand is already fully open.	Switching is triggered after the neutral position has been reached and a certain delay time has passed.

Comparison of the switching methods with the predicate devices:

Co-Contraction:
No differences, all predicate devices and the Axon-Bus Prosthetic System offer Co-Contraction switching mode

Four-Channel Control:
The MyoSystem with Customizing and the Axon-Bus Prosthetic System offer Four-Channel Control for switching between the joints.

Pulse:
The i-limb System uses double and triple impulse for switching. The Axon-Bus Prosthetic System uses single impulse for switching.

Long Open:
The Bebionic System and the Axon-Bus Prosthetic System offer the long opening method for switching between the grip patterns.

Switching when Neutral Position is reached:
No predicate device uses this switching method.

4.5 Technological and Performance Characteristics

System		
Power Source		rechargeable battery
PC Software for adjustment		Yes
Software/Firmware/ Microprocessor Control?		Yes
Hand		
Operating temperature [°C]		-10 to +60
Weight [g]		600 (incl. Passive flexion and rotation)
max. Gripping force (opposition mode) [N]		70
max. Gripping force (lateral mode) [N]		60
max. Gripping force (neutral mode) [N]		15
max. Grip Speed [mm/s]		325
max. Opening Width [mm]		120
Battery		
Chemistry		Li Ion
Number of cells		3
Battery capacity [mAh]		various (1150 / 1500)
Nominal voltage [V]		11,1
Charging time [hrs]		max. 3,5
Battery weight [g]		142
Battery dimensions (LxWxH) [mm]		various (75x60x21 / 55x35x23)
Installation		integrated
Electrode		
Electrode Temp. Range		-15°C to 60°C
Material of Main	Housing	Plastics (ASA)
	Contact Area	Titanium (Grade 1)
	Pad	Silicone
	Bonding Agent	Cyanacrylate
Frequency Bandwidth [Hz]		90 - 450
Adjustment		Potentiometer 1-7
Installation		suspension arms / suction socket
Dimensions [mm]		27 x 18 x 9,5
Elbow		
Elbow Temp. Range [°C]		0 to 60
Automatic Forearm Balance		Yes
Lock		Mechanical, electric

Maximum vertical load with locked elbow joint and a forearm length of 305 mm / 12 inch [kg]	23
Weight [g] (without hand, wrist and battery)	750
Max. forearm length [mm]	305
Flexion angle [°]	15 – 145

The Axon-Bus Prosthetic System offers the following functions:

- Multiple control strategies
  - Different Control Options available for individual patient needs
- Different grip patterns
  - Power grip
  - Three-Point grip
  - Two-Point grip
  - Rest position
  - Two Thumb positions
- Passive wrist functions
- Mechanical and electrical elbow lock

4.6 Comparison to Predicate Devices

The Axon-Bus Prosthetic System has similar intended use and technical features compared to the predicate devices listed above.

4.6.1 Similarities

The subject device shows the following similarities in functional performance:

Available control options:
Similarity: Various control options available for individual patient needs
Description: All devices allow the selection of various control strategies. Regarding application of gripping force and gripping speed all devices allow the selection of proportional control methods. The Axon-Bus Prosthetic System and the MyoSystem with Customizing also allow the selection of digital control methods (time proportional application of gripping force and constant gripping speed).
Regarding number of input channels all devices allow the control via 2 individual electrode signals. Pro Hand System, MyoSystem with Customizing and the Axon-Bus Prosthetic System allow also the control via 1 electrode signal.

Available switching methodes:
Similarity: Various switching methodes available for individual patient needs
Description: All devices allow the patient to switch between various joints and gripping patterns. All devices offer the Co-Contraction switching method. The MyoSystem with Customizing and the Axon-Bus Prosthetic System offer Four-Channel Control for switching between the joints. The Bebionic System and the Axon-Bus Prosthetic System offer the long opening method for switching between the grip patterns.

Available grip patterns:
Similarity: Various grip patterns available for individual patient needs
Description: All devices allow the patient to use various grip patterns. All devices allow power grip which allows holding objects with large diameters. In addition all devices allow a two-point grip, whereby objects can be fixated between two fingers. The Axon-Bus prosthetic System also allows a three point grip (also supported by i-limb System and Bebionic System), which allows the user to fixate small objects. The Axon-Bus Prosthetic System, the i-limb System and the Bebionic System allow the user to switch between 2 individual thumb positions, whereby the users can switch between opposition and lateral grip. The Axon-Bus Prosthetic

System, the i-limb System and the Bebionic System allow the user to use a rest position, which gives the hand a natural and physiological appearance.

Passive wrist functions
Similarity: Passive rotation and flexion of the wrist available
Description: All devices allow the patient to rotate the wrist joint passive. The Pro Hand System and the Axon-Bus Prosthetic System also allow passive flexion of the wrist joint. Due to wrist rotation pro- and supination of the hand is possible.

Mechanical and electrical elbow lock
Similarity: Mechanical and electrical locking mechanism available for the elbow joint
Description: The MyoSystem with Customizing and the Axon-Bus Prosthetic System allow mechanical and electrical lock of the elbow joint. The Bebionic System allows electrical lock of the elbow joint.

4.6.2 Differences and Comparison

The subject device shows the following differences:

Weight of Hand:
Description & Comparison: The Axon-Bus Prosthetic System's hand is a little bit heavier in weight compared to the predicate devices.

Discussion: This is because the Axon-Bus Prosthetic System supports also passive flexion for the wrist..

Grip Forces:
Description & Comparison: Grip forces vary for the different devices.

Discussion: The Axon-Bus Prosthetic System's grip forces for the different types of grips are at least higher than compared to one or more predicate devices. The deviations in grip force do not result in any risk for the user.

Speed:
Description & Comparison: Grip Speed varies for the different devices.

Discussion: The Axon-Bus Prosthetic System's grip speed is higher than compared to all predicate devices and therefore it does not result in any risk for the user.

Battery Characteristics:
Description & Comparison: The Axon-Bus Prosthetic System has a rechargeable Li-Ion Battery Pack with 11,1 V. Most of the predicated devices use rechargeable 7V Li-Ion Battery Packs.

Discussion: The higher capacity and nominal voltage is needed to provide the performance related to grip force and grip speed. This also leads to varieties in charging time, weight and dimensions. None of these deviations do result in any risk for the user.

Material of Electrode Contact Area:

Description & Comparison: The contact area of the Axon-Bus Prosthetic System electrode is made up of titanium (grade 1). The electrode of the predicate device (MyoSystem with Customizing) uses stainless steel

Discussion: Titan is known as a material with good biocompatibility properties, and is therefore very common e.g. for use in implants. Nevertheless, the used material (titanium grade 1) is tested according to biocompatibility requirements of ISO 10993.

Material of other Parts Contacting Patient Skin (Electrode Housing, Silicone Pad):

Description & Comparison: The Housing of the Axon-Bus Prosthetic System Electrode is made up of ASA, whereas the Housing of the predicate device (MyoSystem with Customizing) uses ABS. The Axon-Bus Prosthetic System Electrode uses also a Silicone Pad.

Discussion: The used Silicone Pad is certified according to USP Class VI. In addition, all used materials (ASA, Silicone Pad and Bonding Agent) are tested according to biocompatibility requirements of ISO 10993.

Index-Point Grip:

Difference: The Axon-Bus Prosthetic System does not support an index-point grip.

Description & Comparison: The I-limb System offers an Index-Point Grip: thumb, little, ring and middle fingers close and switch off. Only the index finger will move. This option is particularly useful when operating a computer keyboard, cell phone or elevator button.
The Bebionic System also offers an index-point grip, where middle, ring and small fingers close against the palm and the thumb is driven against the middle finger. Once this position is selected, typing on a keyboard or input pad, pressing a bell or a button can be achieved.
The other predicate devices do not offer this type of grip.

Discussion: This additional available option of the predicate devices is considered only for special activities of daily living (e.g. typing on a computer keyboard, etc.). Therefore the difference in the available grip options does not raise any questions with respect to safety and effectiveness in comparison to the predicate device.

Switching Method – "Pulse":

Difference: The Axon-Bus Prosthetic System offers uses single impulse for switching, whereas the i-limb System uses double and triple impulse for switching.

Description & Comparison: A single impulse (single muscle signal generated by the user) can be selected as switching method for the Axon-Bus Prosthetic System, and as a result the user can switch between different joints and gripping patterns. The i-limb System also allows the selection of a switching method triggered via impulses, but to trigger such a switching the user has to generate double impulses (two uninterrupted muscle signals) or triple impulses (three uninterrupted muscle signals).
The other predicate devices do not offer this type of switching method.

Discussion: This switching method needs only 1 impulse instead of 2 or 3 impulses of the muscle signal. For the user these switching methods differ only in the number of impulses which must be

generated. Therefore this difference in the available switching method does not raise any questions with respect to safety and effectiveness in comparison to the predicate device.

Switching Method – "Automatic Switching after Neutral Position is Reached":
Difference: No predicate device uses this switching method.

Description
& Comparison: This switching method does not require a muscle signal for triggering Switching is triggered after the neutral position of the hand has been reached, and a certain delay time has passed.

Discussion: This switching method is for patients who have a preferred type of grip. So if such a preferred grip type and this switching method are selected, this helps the user to start the next movement always with the preferred type of grip. Therefore this allows the user to control the prosthetic device more efficiently, but it does not raise any questions with respect to safety and effectiveness in comparison to the predicate device.

Positioning of thumb:
Difference: Electrical rotation of the thumb instead of passive rotation

Description
& Comparison: The Axon-Bus Prosthetic System allows the patient to move the thumb lateral to the index fingers so that the user can grip items from the side. This is established electronically, whereas the i-limb System and the Bebionic System allow this lateral movement of the thumb only in a mechanically way.
The MyoSystem with Customizing and the Pro Hand System do not offer this lateral movement of the thumb (neither electronically nor mechanically).
Discussion: The electrical positioning of the thumb does not require the other hand of the patient for moving the thumb. Therefore this feature helps the patient to control the prosthetic device more efficiently, but it does not raise any questions with respect to safety and effectiveness in comparison to the predicate device.

4.6.3 Conclusion of Comparison to Predicate Devices:

All patient contacting materials of the Axon-Bus Prosthetic System are equivalent to those of the predicates and are in compliance with ISO 10993-1. The subject device is also substantially equivalent to its predicates based on comparison of functional and performance characteristics. The differences of the subject device don't raise any questions with respect to safety and effectiveness of the device.

5 Indications for Use

The Axon-Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.

6 Summary of Performance Testing

The following Performance Standards were used for performance testing of the Axon-Bus Prosthetic System:

No.	Title	Version	Comments
ISO 22523	External limb prostheses and external orthoses - Requirements and test methods	2006-10-01	-
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005	Protection against electrical hazards from ME equipment: Classification according to chapter 6, testing according to chapter 8.
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	2007	Electromagnetic Compatibility
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2009	Biocompatibility
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009	
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2009	
EN 980	Symbols for use in the labeling of medical devices	2008	Labeling Symbols
IEC 60721-3-2	Classification of environmental conditions Part 3: Classification of groups of environmental parameters and their severities - Section 2: Transport	1997	Shipping test
IEC 60068-2-1	Environmental testing Part 2-1: Tests – Test A: Cold	2007	
IEC 60068-2-2	Environmental testing Part 2-2: Tests – Test B: Dry heat	2007	
IEC 60068-2-30	Environmental testing Part 2-30: Tests – Test Db: Damp heat, cyclic (12 + 12-hour cycle)	2005	
IEC 60068-2-78	Environmental testing Part 2-78: Tests – Test Cab: Damp heat, steady state	2001	
IEC 60068-2-14	Environmental testing Part 2: Tests – Test N: Change of temperature	1986	
IEC 68-2-64 (EN 60068-2-64)	Environmental testing Part 2-64: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance	1993	
IEC 68-2-27 (EN 60068-2-27)	Environmental testing Part 2-27: Tests – Test Ea and guidance: Shock	1987	
IEC 68-2-32 (EN 60068-2-32)	Basic environmental testing procedures Part 2: Tests – Test Ed: Free fall	1990	

Table 1: Standards used for performance testing

Extensive testing was performed (e.g. software testing and electrical safety tests including EMC). Also biocompatibility testing according to ISO 10993-1 was performed on all patient contacting materials. No clinical studies were performed. Since all samples tested met the acceptance criteria, substantial equivalence has been demonstrated through these tests.

In Addition, internal testing regarding performance characteristics of the hand, wrist and elbow has been conducted on the Axon-Bus Prosthetic System to ensure that the device meets design specifications, operates as it is intended, and ensures that safety functions and features operate as they are intended.

Component	Performance Attribute	Test Result
Hand	Weight of the prosthesis	Passed
	Compatibility of components	Passed
	Activating and deactivating the system	Passed
	Performing different types of grips	Passed
	Gripping different sizes of objects, max. opening distance	Passed
	Grip force (strength, increase and decrease, maintaining grip force when engine not running)	Passed
	Positioning speed	Passed
	Emergency opening	Passed
	Mechanical strength (static and dynamic testing)	Passed
Wrist	Positions of flexion and rotation unit	Passed
	Mechanical strength (static and dynamic testing, support a specific weight)	Passed
	Connecting/ disconnecting of flexion adapter to/from rotation adapter	Passed
Elbow	Mechanical strength (static and dynamic testing)	Passed
	Maintaining position (Maximum holding force): Overload Protection	Passed
Tube Valve	Function of Tube Valve for Suction Socket	Passed

Table 2: Overview of internal testing regarding performance characteristics

All tests that has been conducted on the Axon-Bus Prosthetic System to ensure that the device meets design specifications, operates as it is intended, and ensures that safety functions and features operate as they are intended were passed.

7 Conclusion

The Axon-Bus Prosthetic System is safe and effective for its intended use. The Axon-Bus Prosthetic System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 3, 2014

Otto Bock Health Care Products
Reinhard Wolkerstorfer
Regulatory Affairs Manager
Kaiserstrasse 39
1070 Vienna
AUSTRIA

Re: K123795
Trade Name: Axon-Bus Prosthetic System
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: May 20, 2014
Received: May 23, 2014

Dear Mr. Wolkerstorfer:

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 contact 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. 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,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K123795

Device Name
Axon-Bus Prosthetic System

Indications for Use *(Describe)*
The Axon-Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.06.03 21:19:23 -04'00'

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