REGULATORY INFORMATION

FDA identifies this generic type of device as:

Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components. An Upper Extremity Prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.

NEW REGULATION NUMBER: **21 CFR 890.3450**

CLASSIFICATION: **II**

PRODUCT CODE*:* **PAE**

BACKGROUND

DEVICE NAME*:* **DEKA ARM SYSTEM**

SUBMISSION NUMBER*:* **DEN120016**

DATE OF DE NOVO*:* **JUNE 14, 2012**

REQUESTOR CONTACT*:*   **ROGER LEROUX**
                                     340 COMMERCIAL STREET
                                     MANCHESTER, NH 03101

REQUESTOR'S RECOMMENDED CLASSIFICATION: **II**

INDICATIONS FOR USE

The DEKA Arm System consists of a prosthetic arm and accessories, which are used by a certified prosthetist to create a full upper extremity prosthesis indicated for individuals, age 18 years and older, who have partial or full upper limb amputations or congenital defects. The device is used to assist in activities of daily living (ADLs).

The DEKA Arm System is indicated for Prescription Use.

LIMITATIONS

The DEKA arm has the following key Cautions and Warnings:

Warnings
- The safety and effectiveness of the DEKA Arm System has not been established for bilateral amputees that include a unilateral or bilateral transhumeral or scapulothoracic level of amputation.
- Do not use the arm if it or any of the arm's parts have been damaged. This can lead to harm. Contact your prosthetist and have the damaged part(s) serviced.
- Use care when handling hot liquids with the arm.
- Do not touch live electric wires with the arm.
- Use extreme care when using the arm near any type of heavy machines. Getting the arm trapped in a machine can pull you in.
- Do not use the arm to drive a car or truck or other motor vehicle. Moving the arm in the wrong way can lead to loss of control.
- Use extreme care when picking up or holding sharp or heavy objects with the arm. Moving the arm in the wrong way can lead to dropping these items or hitting someone nearby with these items.
- Do not take apart or change the arm or connected parts. This could lead to harm.
- The arm should be kept away from anesthetics, oxygen rich areas, and flammable liquids.
- If you are unable to reliably press the hand open button, take extra care when grasping items. Failure to release the item using the hand open button could lead to injury.
- Use care when using the arm near sources of heat or open flame such as heaters, fireplaces and stove burners. Getting too close to these items could cause the arm to catch fire and lead to injury.
- When getting medical care, remove the arm. Contact with or being close to medical hardware can cause the arm to move or lead to electric shocks.
- MRI Safety Information: The arm is MR Unsafe. Remove the arm before entering an MRI scan room. Contact with or being in proximity to an MRI scanner can cause the arm to move or lead to electric shocks and may result in severe injury.

Cautions
- The arm system has been designed for activities of daily living. This includes such tasks as moving a gallon of milk around and carrying heavy loads (a 20-lb bag of groceries, for instance). The amount of weight that can be carried or moved using the arm system also depends on the fit of your socket, your body's ability to support the load, and your arm position. Use caution when lifting or carrying a heavy load with the arm which you haven't carried before.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

Hardware and Motor output:

The DEKA Arm System is a lithium-ion battery operated upper limb prosthesis intended to restore limb functions in individuals who lost all (i.e., shoulder disarticulations) or part of either upper limb (e.g., trans-radial amputation).

Figure 1 - DEKA Arm System

Three configurations may exist, depending on the level of amputation or congenital defect. These are:
- shoulder configuration (SC) for shoulder disarticulations,
- humeral configuration (HC) for humeral disarticulations, and
- radial configuration (RC) for radial disarticulations.

The external battery (RC configuration only, and SC/HC configuration with only external battery), and SC/HC configuration (with an internal battery) have ON/OFF switches: soft Off when held down for 1-2 seconds, hard Off at 8 seconds. The arm is applied using standard fitting and fabrication techniques. It can provide up to 10 active degrees of freedom, including:
- shoulder abduction
- shoulder flexion/extension
- humeral rotation
- elbow flexion/extension
- wrist pronation/supination
- wrist flexion/extension
- index finger flexion/extension
- flexion/extension of other fingers
- thumb flexion/extension, and
- thumb abduction/adduction.

Main components consist of (see Figure 2 below):
- Mechanical limb hardware,
- Arm Control Interfaces (ACI) that record user input signals (myoelectric recording electrodes, discrete bump switches, linear transducers, Inertial Measurement Units (IMUs), and force sensing resistors),
- Inertial Measurement Units (IMU) that record arm and foot movements,
- Master Arm Controller (MAC) that is the main processor,
- Arm Control Modules (ACM)/Hand Control Module (HCM) that control movement and are used for each respective limb component, and
- One or more battery modules and holsters.

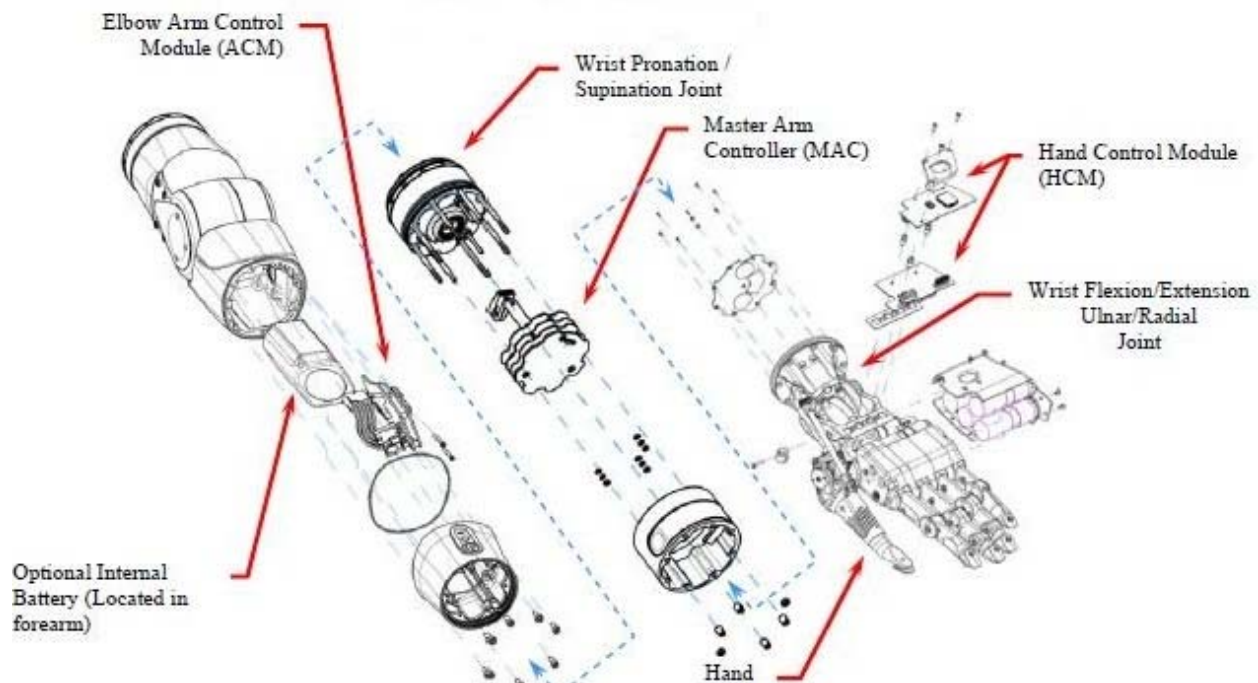The IMUs and force sensing resistors are preferably placed in the shoes or on the feet.

Figure 2 - DEKA Arm System components

These components communicate via the Controller Area Network (CAN). The device is powered through a separate power bus. The system, not including the IMUs, is IP52 rated (small dust and light rain impermeable). The MAC controls wrist movement only, but oversees all actuators. There is afferent and efferent communication between the MAC and ACMs, HCM, IMUs, ACIs and battery module. The ACMs control actuators above the wrist while the HCM controls actuators below the wrist. The battery module may be embedded inside the arm, or worn outside the arm. IMUs do have a Power Control Module for the battery and are IP57 liquid/particle ingress rated.

The hand has a grip release button that will release the grip in emergencies. Because of the importance of this safety feature, there are two buttons present to add redundancy. When either

button is pressed for 5 seconds, it releases the brakes in the shoulder, humeral rotator and elbow (if present), and allows the arm to be manually repositioned.

Wireless and "Sensory" input:
The arm communicates wirelessly via 2 RF channels to a personal computer (PC) for configuration, as well as up to two IMUs. The 2 antennas for the PC link are located in the MAC, while the IMU antenna is located in the wrist.

Signal acquisition from the user may be derived from cutaneous myoelectric recording electrodes, discrete bump switches, linear transducers, IMUs, and force sensing resistors, with the ability to accommodate 4 inputs (including up to 2 wireless inputs). Each of the 4 input methods may use up to 4 channels each.

Wireless input comes only from the IMUs. These are positioned to sense gait position and to have the arm respond accordingly by disabling the present mode and IMU motion control and thereby moving with gait. The IMUs are ignored during walking, and users are instructed to put the arm into standby mode while walking. IMUs are activated by shaking, and will consider a standing position to be whatever the orientation of the foot is when the device is brought out of standby. Wired input is acquired through the ACIs and transmitted to the MAC. In order for these 4 inputs to control the 10 degrees of freedom, modes are used. The user may choose between 3 modes, which are initiated by a predefined input from one of the 4 inputs (e.g., muscle twitch, but not the IMUs) and include:

- Standby: the arm is on, and ready to be put into a mode; no movement is possible.
- Hand: the inputs will control hand and wrist movements.
- Arm: the inputs will control arm movements (proximal and including the elbow).

The RC configuration can use Hand and Standby modes, while the other configurations can use Hand, Arm or Standby modes. These modes include only certain degrees of freedom, as listed above. The Hand mode is also called simultaneous mode. The Standby mode is set by holding the mode select input to threshold for 1–3 (configurable) seconds. Furthermore, for bidirectional movements, 2 electrodes must be used, while only 1 IMU or switch is necessary. Note - IMUs may put the device in standby during walking or make bidirectional arm movements.

Feedback will be provided by a tactor, which will be used to provide vibration feedback (for grip strength and/or mode changes) to the user, and LED control display on the arm (which displays battery status, grip status, mode selected, and alerts). If both internal and external batteries are used, then the battery charge shown is the combined charge. The LED display contains redundant icons on both sides of the arm, so that it may be seen easier depending on how the arm is positioned.

EMG Electrode Information:
The cutaneous EMG electrodes were cleared in K032833. Based on the information in K032833, these electrodes are intended for EMG applications and contain 3 terminals and a differential pre-amp. The contacts are gold-plated. Electrodes may only be placed in the socket or harness.

Lithium Ion Polymer Batteries:
There are three batteries that may be used with this device: an internal battery, an external battery, and an IMU battery. Each is a lithium ion battery. The internal battery and the IMU battery are technician replaceable only, the external is user replaceable. One battery may exist in the forearm for either the SC or HC configuration. The external battery is used in any configuration including the third RC.

Fault Safety
During a fault or shutdown, the arm slows or stops   depending on the present action, while the hand will only stop. All sensory input is ignored, except for the emergency hand open button. To mitigate aberrant action, the arm is limited in joint speed. The speed is further reduced when movement is bringing the hand towards the face as detected by the angles of the joints. The IMUs are designed to detect a fall, and command the MAC to ignore all inputs. Grip may only be changed when the hand is within 10% of fully open. If there is an interruption of less than 0.5 seconds with the IMUs, the motions of the arm will be stopped. If this continues to 2 seconds, the arm resets to Standby mode. If a joint is commanded to move, but fails due to being overloaded, the arm is designed to prevent whipping when the load is removed. If the device encounters a failure, it reverts to a safe state; this is possible while carrying a payload of less than 3.9 kg. A load of 3.9 ± 0.1 kg is used in testing to ensure all joints are able to move their full range with this load.

SUMMARY OF NONCLINICAL/BENCH STUDIES

A. MECHANICAL/DURABILITY TESTING

The sponsor provided durability testing as a mitigation for some risks listed in their risk analysis. Durability testing was completed on 2 samples, although some samples received maintenance service after 18 months of accelerated life-time testing use, since certain components were not able to withstand a 3 year test. To simulate usage over three years, the durability testing in question involves cycling the arm several times (4,000 and 28,000 times, depending on the test) through different types of movement (e.g., turning door knobs, moving objects from tables to shelves). Mechanical strength testing from IEC 60601-1:2005 Sec. 15.3 was conducted. Many of the risks mitigated with durability testing are mitigated through other means as well (e.g., IEC 60601-1, 60529 testing). Testing was acceptable since all criteria of the standards were met, and durability testing demonstrated when maintenance will be necessary. Labeling was updated accordingly.

B. BIOCOMPATIBILITY/MATERIALS

The sponsor performed an evaluation of the patient contacting materials. The electrodes were previously cleared (K032833) and were previously evaluated for and found to successfully pass biocompatibility testing. Most other DEKA arm parts are incidentally contacting, and not intended to have prolonged contact with the skin. Only the socket has prolonged contact, and is a standard fitting using standard fitting materials and standard prosthetic procedures. The materials used in the socket have had skin irritation,

sensitization and cytotoxicity testing performed per ISO 10993. The materials in the arm and the socket are well characterized in prosthetic applications, and do not require additional biocompatibility testing as part of this submission.

C. SHELF LIFE/STERILITY

Neither the device nor the components are provided sterile nor is this necessary for this device.

The sponsor states in the labeling the device shall have a service life of 3 years, with a servicing at 18 months. The sponsor notes that the user should: "Periodically clean the arm with a wash cloth wetted with water and a mild soap such as hand soap." These cleaning instructions are similar to other prosthetic devices, and are also appropriate for this device, particularly because it has an IP52 rating.

D. ELECTRICAL TESTING

1. LEAKAGE CURRENTS

Leakage current tests from IEC 60601-1: Sec. 8.7 are within specification and acceptable (this includes when using mains power).

2. ELECTROMAGNETIC COMPATIBILITY (EMC) AND ELECTRICAL SAFETY

Testing was performed to address EMC concerns for this device which is intended to be used in a wide variety of environments. Each test was performed for multiple arm configurations on the production-ready version. The sponsor determined the basic safety and essential performance of their device per IEC 60601-1: to determine the compliance criteria which were applied for all tests in the EMC Test Summary table (see Table 1). All tests were performed and passed to the most recent recognized version of IEC 60601-1-2: with test levels appropriate for the home use environment. Additional tests were carried out to account for specific emitters not fully covered by IEC 60601-1-2: (labeled as FDA RF Wireless Guidance in Table 1).

Table 1 - EMC Test Summary

EMC Test Summary			
Test Method	Frequency	Level	Finding
Emissions			
BS EN 55011:2009	150-30000 kHz	Group 1 Class B	Pass
BS EN 55011:2009	30-1000 MHz	Group 1 Class B	Pass
47 CFR 15.249	1-40 GHz	N/A	Pass
Immunity			
IEC 61000-4-2 (contact)	N/A	±2, ±4, & ±6 kV	Pass
IEC 61000-4-2 (air)	N/A	±2, ±4, & ±8 kV	Pass
IEC 61000-4-3	80 - 2500 MHz	3V/m	Pass
IEC 61000-4-4	N/A	±2 kV	Pass
IEC 61000-4-5	N/A	±1 & ±2 kV	Pass
IEC 61000-4-6	150 - 80000 kHz	3V$_{RMS}$	Pass
IEC 61000-4-8	50 & 60 Hz	3A/m	Pass
IEC 61000-4-11	N/A	N/A	Pass
FDA RF Wireless Guidance[8]	100 - 3500 Hz[1]	300A/m	Pass
FDA RF Wireless Guidance[8]	10 - 60 kHz[2]	50A/m	Pass
FDA RF Wireless Guidance[8]	50 - 150 kHz[2]	30A/m	Pass
FDA RF Wireless Guidance[8]	26 - 80 MHz[3]	10V/m	Pass
FDA RF Wireless Guidance[8]	460 - 470 MHz[4]	10V/m	Pass
FDA RF Wireless Guidance[8]	690 - 965 MHz[5]	20V/m	Pass
FDA RF Wireless Guidance[8]	1390 - 6000 MHz[6]	20V/m	Pass
FDA RF Wireless Guidance[8]	2400 - 2500 MHz[7]	10V/m	Pass

Basic Safety and Essential Performance included:

- During operation of the prosthesis by the wearer, a failure in communication between control modules shall result in the prosthesis reverting to a safe state.
- During operation of the prosthesis by the wearer, a detectable failure or out of range reading of any sensor or motor shall result in the prosthesis reverting to a safe state.
- When power is removed from the prosthesis system, the prosthesis system shall revert to a safe state.
- The prosthesis system shall provide a means to the user to turn the prosthesis power on and off.
- The prosthesis system shall slow gross movements of the terminal device to 130 mm/second or less, averaged over a time interval of 1.00 s ± 0.25 s, when moving toward the wearer's face at distances of 65 mm or less.
- The terminal device shall have a manual release feature that allows the terminal device to release its grasp without the use of a tool in less than 10 seconds while power is applied to the prosthesis.
- Upon power up, the system shall default to Standby mode.
- IMUs shall not command motion if rotated more than 50° in either the pitch or roll axes relative to the orientation at which the system was last brought out of standby.
- The HC configurations of the prosthesis system shall limit elbow flex speed to less than 10°/s when within 5° of the limit of elbow flexion.
- During normal operation, the system shall leave the white and blue LEDs on the wrist-mounted display off when the system is in Standby mode of operation and not displaying state of battery charge.
- During normal operation, the system shall illuminate the white LED at the user selected illumination level on the wrist-mounted display when the system is the Arm mode of operation and not displaying state of battery charge.

3. BATTERY TESTING

Three batteries may be used with the device: external battery, the internal battery and the IMU battery.

- The internal battery uses a b(4) electrolyte, which holds b(4) mAh, which may deliver up to 12A and has a nominal voltage of 14.8 V (there are four 3.7 V cells). A 3-state charger is used, which is built into the arm takes 2 hours to charge to 80%. The external battery or an AC transformer may be used in supplying current at 24 VDC. The arm may be activated and used while mains charge the internal battery. The external and IMU battery are separated from the device during charging.

- The external battery uses 8 cells (4 rows of 2 parallel cells). The external battery uses a b(4) , holds b(4) mAh, which may deliver up to 12 A, and has a nominal voltage of 14.8 V. It takes 2 hours to charge to 80%. The specifications for the batteries and chargers were provided. The usual

safety mechanisms a 15A fast acting fuse are used with this battery. The cells were evaluated to UL 1642 (a test report for IEC 62133:2002 was also provided with only passing results) and the battery was evaluated to IEC 60601-1:2005.

- The IMU battery is a lithium polymer (Li-Po) battery, has a b(4) electrolyte, holds 190 mAh, may deliver up to 0.38 A, and has a nominal voltage of 3.7 V. The IMU battery is charged via an inductive Qi version 1.1 charging pad, and takes 2 hrs to charge to 80%. It uses the same standards for Verification & Validation as the other batteries above.

Battery testing was conducted to demonstrate the device is sufficiently able to detect when the battery is low on capacity (the level of detection is determined by the configuration of the arm). Low battery testing demonstrated adequate detection of a low battery. The battery is in a low battery state when it has ~15 minutes of life left. The arm has an alarm, and notable slowing of the arm will occur to advise the user the arm is low on power.

E. MAGNETIC RESONANCE (MR) COMPATIBILITY

The DEKA arm device system is labeled as MR Unsafe. Testing for determining the MR compatibility was not conducted for the device.

F. SOFTWARE

The software/firmware was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

The software is determined to be a moderate level of concern. It is divided into internal (Luke Software) and external (Prosthetist Interface (PI)) applications; the external software is run on a PC computer. The software applications adapt the device to the specific configuration needed by the patient for optimum performance. Since the wireless communications with the PC are checksummed, safety and essential performance should be maintained in the event of a fault.

1. PI SOFTWARE
The arm may be configured to perform a sequence of movements in response to a single type of EMG (electrode) input. EMG (and other input) data are interpreted as either analog (low to high value) or digital (on and off). Whether analog or digital is chosen for a movement is based on the user's unique circumstances. Configuration is done in 5 steps by the PI software, and can save and setup more than one arm. The software includes a virtual reality environment for testing the input commands of the arm. A 3D representation of the patient and arm demonstrates how the arm will move when certain inputs are activated (e.g., EMG detection of muscle contraction).

2. LUKE ARM SOFTWARE

The Gen 3 MAC software interprets the signal inputs, and in turn controls the HCM or ACM. HCM or ACM software interprets data from the MAC and feeds it data from sensors. The ACM controls arm movement, while the ACI pre-processes data from the sensors.

All software was appropriately validated.

G. OTHER NONCLINICAL PERFORMANCE TESTS

Concerns about electrode placement, retention, and fluid tolerance were adequately addressed by usability testing (see the Summary of Clinical Information section) of the SC configuration during times of physical exertion and sweating, which was determined to be the worst case scenario for this testing.

The following identify other notable nonclinical performance tests that were conducted by the sponsor:

- The sponsor used IEC 60601-2-40 for EMG related tests, although the sponsor did not assess for evoked response related clauses, which was deemed appropriate.
- Abuse testing (consolidation of shock and impact testing) was included (and done according to several sections of IEC 60601-1-11 2010 and IEC 60601-1:2005 Sec. 15.3).
- IP52 testing was documented (the IMU is IP57 rated) and done in accordance with IEC 60529.
- Testing of the face approach velocity slowdown was done. The sponsor tested the arm from various initial positions (from the front, side and above the head) to accurately test the ability of the arm to detect the position.
- ACI and IMU communication loss testing was done.
- Sudden power loss testing, ensuring the defined safe state is reached, was performed.
- The hand open button (previously manual release) was tested with different grips. The sponsor recommends it be tested monthly.
- The sponsor provided an analysis of the doffing time, which found an average doffing time of 14.4 and 17.6 seconds for the SC and HC configurations, respectively.

The device passed all of these tests, and the results were found to be acceptable.

SUMMARY OF CLINICAL INFORMATION

Over the course of clinical studies, the Arm was modified from Generation 2 (Gen2) to Generation 3 (Gen3), the version to be marketed. The testing below includes subjects who used the Gen2 arm and Gen3 arm. The Gen3 arm was changed to include:

- a wrist with the combined movements of flexion/extension with ulnar/radial deviation
- smaller IMUs
- updated pressure transducer
- increased shoulder abductor speed
- increased battery capacity
- control module integrated into forearm
- reduced size of arm control interface
- decreased size of hand palm
- shoulder mount changed from horizontal to vertical

FDA believes the data collected on the Gen2 system can be used to support the safety and effectiveness of the Gen3 arm because the changes listed above are improvements made based on feedback received during device testing and do not adversely affect the safety or effectiveness of the device.

A. Study 1: Veterans Affairs (VA) Study to Optimize the DEKA Arm: Research Design And Analytical Methods

1. Objectives
Although the VA reported multiple aims in the study, the aims most relevant to determining reasonable assurance of safety and effectiveness of the device are as follows:
1. Evaluate the usability of the Gen2 DEKA Arm and Gen3 DEKA Arm prototypes
2. Quantify the dexterity, prosthetic skill, spontaneity of prosthetic use, performance of daily activities and device satisfaction of amputee users of the DEKA Arm
3. Compare scores of dexterity, prosthetic skill, spontaneity of prosthetic use, performance of daily activities and device satisfaction tests when using the DEKA Arm to scores using the existing prosthesis

2. Methods
The VA described their study as an iterative usability and optimization study with repeated measures collected prior to and after users received the DEKA Arm. It employed a multiple case study design using a mixed-methodology (quantitative and qualitative) approach. Multiple endpoints included 5 performance-based and 6 self-report measures obtained at 5 time points: baseline (twice), at finalization of arm set up, and after the 5th, 10th and 15th (for shoulder configuration (SC) arm only) training sessions depending on the arm configuration. There were approximately 21 visits for each user. Some subjects with SC configuration had an additional 6 visits: training sessions 11-15 plus one testing visit.

3. Participants
Thirty-six (36) arm users were purposively sampled in the VA Study to represent amputation levels appropriate for device. Enrollment began using the Gen2 version of the DEKA Arm System. During the course of the study a modified version of the arm (Gen3) was implemented. A representative number of subjects using each configuration were also studied. The breakdown of the number of subjects and versions of the arm by configuration tested are given below:

Gen 2 (26 subjects)
- RC: 8
- HC: 8
- SC: 10

Gen 3 (10 subjects)
- RC: 3
- HC: 4
- SC: 3

Repeat participation was allowed for bilateral users (each side contributed data), unilateral users that could be fit with two different configurations, or users of earlier versions that may have yielded different results (e.g., five Gen2 users participated in Gen3 study).

4. **Outcome Measures**

Dexterity, Performance, and Satisfaction Test /Measures	Type of Test	Brief Description and Scoring
Modified Box and Blocks Test of Manual Dexterity	Performance - dexterity	Generic test that measures the number of blocks moved in 60 seconds. Reported in blocks/60secs
Jebsen-Taylor Hand Function Test	Performance - dexterity	Seven part dexterity test that evaluates how many events of each sub-task are completed in 2 minutes. Reported in tasks completed in 2 min and tasks/sec.
UNB - University of New Brunswick Test of Prosthetic Function (not presented)	Performance-functional activities	Performance of ten adult tasks with performance score based on spontaneity and skill of prosthetic function.
AM-ULA - Activities Measure for Upper Limb Amputees (VA developed mid study, 2 measures below related)	Performance-functional activities	Performance of 18 items of daily activity. Rating based on ability to complete task, speed, movement quality, skillfulness, and independence. Scale: 0=unable, 1=poor performance, 2=fair performance, 3=good performance–similar to natural extremity
Activities Performance Measure (VA developed for Gen3)	Performance-functional activities	Observation of successful (1) or unsuccessful (0) completion of 24 item task list.
Extended Activities Measure (VA developed for	Performance-functional activities	Observation of successful (1) or unsuccessful (0) completion of 11 item task list of challenging activities.

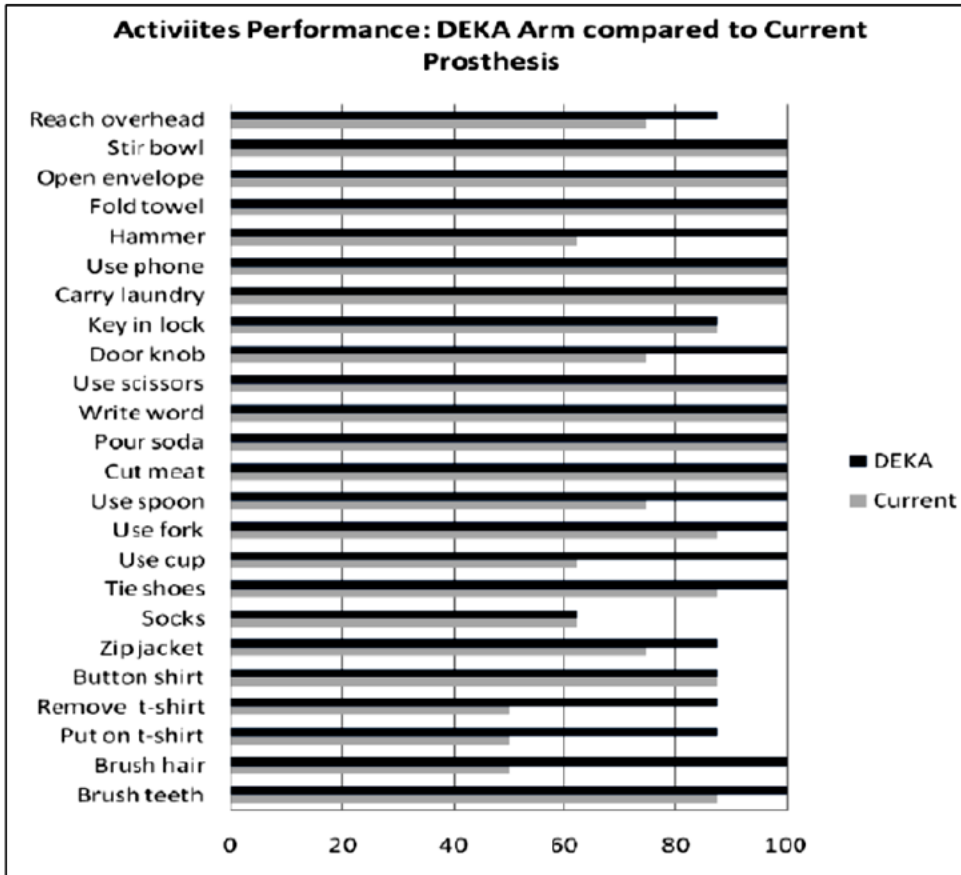| Gen3)		
UEFS - Upper Extremity Functional Scale	Self-report	Subject rates the ease of performing 23 activities using a 5 point scale (1-very easy, 5-can't perform)
UEFS Use Scale	Self-report	Similar to UEFS but ask if the subject would use their prosthesis or DEKA arm to perform the activity. Score is proportion of activities that subject indicated they would perform with the prosthesis.
PSFS - Patient Specific Functional Scale	Self-report	Outcome measure to assess functional status based on subject identifying five activities that are difficult to perform and how this situation improves with the prosthesis (0-unable to perform, 10-perform with no problem)
TAPES - Trinity Amputations and Prosthetics Experience Scale	Self-report	Primarily assesses psychosocial adjustment, activity restriction, and satisfaction with the prosthesis. 10 items assessed with 5 point scale with (1-very dissatisfied, and 5-very satisfied)
DEKA Arm Satisfaction Scale	Self-report	Twenty four item survey to measure satisfaction with features of the DEKA arm on a six point scale (1-very unhappy, 7-very happy)
DEKA Arm Usability Scale	Self-report	Twenty item survey to rate ease of use of the DEKA arm controls, sensors, harnesses and grip. (1-unable to do, 6-very easy)
Prosthetist Rating Scale (not presented)	Prosthetist report	Prosthetist evaluation of ease of fitting and setup of the DEKA arm system (0-unable, 5-very easy)
Therapist Rating Scale (not presented)	Therapist report	Therapist evaluation of ease of training and aspects of the DEKA arm's function (0-unable, 5-very easy)
Open Ended Survey Questions	Interview	Experience participating in study, process of fitting, overall impression, and ease of use of the DEKA arm.

5. Results

Of the 36 subjects enrolled, 29 subjects completed all objective testing. Seven subjects terminated early due to poor attendance (2), scheduling/repair issues (4), and no explanation (1). Some of these subjects completed a subset of the tests.

DEKA Arm Overall
Combined performance and satisfaction with all configurations and versions of the DEKA Arm were compared to the current prosthesis in 26 subjects with a paired t-test. Subjects compared the DEKA Arm (Gen3) performance versus their current prosthesis performance for specific activities; please see Figure 3 for the results on the percentage of

subjects able to complete the tasks with their current prosthesis vs. the DEKA Arm (Gen3). Subjects also rated their preference for using the DEKA Arm (combined and each version: Gen2 and Gen3) versus their current prosthesis for specific activities; please see Table 2 for the results. A rationale was provided for excluding 3 subjects with end of study data for reasons other than performance with the DEKA Arm. For the 8 performance measures reported, function was significantly slower with the DEKA Arm on 2 measures (Box and Block and the Jebsen feeding tests). Two of 4 self-report measures were significantly better with the DEKA Arm (UEFS Use and the Patient Specific Functional Scale).

Figure 3 - Comparison of Activities Performance of DEKA Arm (Gen3) compared to Current Prosthesis

Table 2 - Prosthetic Preference for Specific Activities

Preference	Gen2 (N=21)	Gen3 (N=9)	All (N=30)	Examples
DEKA Arm System	81%	89%	83%	Everything, housework, cooking, any activity involving wrist rotation and flexion, picking up granddaughter, holding a trumpet, feeding myself, getting items out of refrigerator, playing cards, reaching overhead, anything with fine pinch grip, drinking liquids, pushing a mower, using scissors
Current Prosthesis	24%	67%	37%	Any small task due to finger size, running, things that require a light touch, rock climbing, carrying heavy objects, activities that require waterproofing, activities that might cut or damage the hand covering

Arm Version

All of the 9 Gen3 users who were tested at the end of the study were able to perform 18 of 35 every day activities from the Activities Performance Measure and the Extended Activities Measure with the DEKA Arm. The most difficult activity was removing or replacing a wallet from a back pocket. Data were not provided for the Gen2 version of the device for these measures because the assessment tool was implemented for the Gen3 portion of the study. Differences between arm versions were plotted graphically for the other performance and self-report measures, but not compared statistically. Patient reported measures tended to favor Gen3 across all configurations. Performance measures showed more mixed trends across configurations and versions, but for the RC configuration, performance tended to be better for the Gen3 users than the Gen2 users.

Arm Configuration

The results of Wilcoxon signed-ranks tests show that performance with the DEKA Arm compared to the subject's current prosthesis varied by arm configuration for some tests with no clear trends emerging. Self-report measures revealed that users of all configurations performed significantly more activities and reported less difficulty with activities that were important to them when using the DEKA Arm as compared to their current prosthesis. Comparison of within DEKA Arm scores with Kruskal-Wallis tests showed that dexterity and activity performance was consistently better for RC users as compared to HC and SC users. No differences were observed for the self-report measures.

6. **Effectiveness/Self-Report Measures**

The VA study asked users several questions about their impressions of the DEKA Arm. Results highlighted the following:

- 77% of participants said "yes" they wanted to receive a DEKA Arm in the future.

- All Gen 3 users indicated that either they wanted to receive or might want to receive a DEKA Arm in the future.
- Participants that were unequivocally favorable of the device or favorable with critical suggestions varied by configuration: SC 92% or 12/13; HC 73% or 8/11; and RC 82% or 9/11.
  - HC users expressed the highest percentage of responses that were unfavorable (27%, 3/11). HC configuration users also accounted for nearly all of those who failed to complete the study.
- Participants who were generally favorable but had critical feedback commented on issues such as: weight, reliability (breakage and need for repair), range of motion (ROM) of the wrist, and the need to put the arm in standby while walking.
- Four Gen2 participants (16%), including at least one user of each configuration, and two Gen3 participants (20%) had unfavorable impressions of the DEKA Arm at the end of the study.
- Although all Gen3 users expressed an interest in using the prosthesis in the future, they also expressed concerns about taking the arm home.
- At the end of the study, the majority of participants expressed some type of concern about using a DEKA Arm at home. All Gen 3 RC users expressed concern about breakage and need for repair.

Table 3 - Concerns Expressed by Subjects

Concern	Gen2	Gen3
No concern	16%	0%
Some concern	84%	100%
Concerns:		
-Breakage/repair/reliability	44%	60%
-Unintended stoppages/safety	20%	40%
-Getting it wet	24%	20%
-Independent donning/doffing	24%	20%
-Too many wires/cables	16%	10%
-Controls	12%	10%
-Weight	24%	0%
-Too big/bulky	12%	0%
-Other	28%	10%

B. Study 2: DEKA Study: Evaluation of a Multi-Articulated Upper Limb Prosthesis Using Advanced Control Systems

The DEKA study focused on unstructured prosthesis use across a broad range of user-defined activities and was documented through interviews with open-ended and Likert scale questions. Ten (10) arm users were studied in the DEKA Study. DEKA reports that their studies include 3,000 hours of total use time by their participants, including a home use portion that allowed each participant to use the device at home for a two-week interval.

1. **Arm Versions Tested**
   - 5 subjects used both the Gen2 and the Gen3,
   - 1 subject used Gen2 only, and
   - 4 subjects used Gen 3 only.

   All 9 Gen3 subjects used prostheses with IMUs; 3 of 6 Gen2 subjects used prostheses with IMUs, while the other 3 used prostheses with foot pads.

2. **Participants**
   - 10 individuals.
   - 7 unilateral and 3 bilateral amputees. One of the ten amputees also participated in the VA study and had received more extensive training in use of the arm than the other DEKA study participants.
   - 1 RC user only contributed data from a Gen2 arm version with foot pads not IMUs. Two other users that contributed data from a Gen2 arm with foot pads also contributed data from another arm with IMUs.

3. **Arm Configurations Tested**
   - 2 SC, 5 HC, 2 RC

   - SC –
   4 users*; 1 bilateral, 2 unilateral; 2 right, 3 left
   3 tests; 3 Gen3 with IMUs; 2 Gen2 with foot pads

   - HC –
   5 users*; 1 bilateral, 4 unilateral; 1 right, 4 left side
   7 tests; 4 Gen3 with IMUs; 3 Gen2, 1 with foot pads, 2 with IMUs

   - RC –
   2 users*; 2 bilateral, 0 unilateral;
   3 tests; 1 Gen3 with IMUs; 1 Gen2 with foot pads and 1 Gen2 with IMU

   * Bilateral amputees of different amputation levels used arms of different configurations on each side, so numbers of users exceed number of individual participants.

4. **Outcome Data**
   Given the small sample size and usability study aims, the study methods utilized daily interviews of participants during the home use portion of the study. Another set of questions was asked at the end of the two week home use study. The questionnaire and scales were developed by the sponsor and has not undergone external validation.

5. **Effectiveness/Home Use Study**
   Participants using the Gen2 arm version found the device to be comfortable and wore it on average of 7 hours per day (range 2-16 hrs). Participants reported that the arm system

was better at performing tasks than their existing prosthesis. Reliability was reported as being fair to good.

Participants using the Gen3 arm version found the device to be comfortable, and often slightly more comfortable than their existing prosthesis. They wore the prosthesis on average of 6 hours per day (range 3.5-12 hrs) during the take-home study. As with the Gen2 participants, Gen3 participants reported that the arm system was better at performing tasks than their existing prosthesis. Reliability was reported as fair, but there was a significant improvement for the last 4 subjects with reliability average slightly less than excellent.

Activities selected by the participants during take-home studies included activities such as carrying large bales of hay, large pails of water, and cleaning and repair work around horse stalls. Feedback on the needs of these heavy users was used to make design changes to better accommodate these more aggressive user tasks.

The VA and DEKA studies reasonably demonstrate the safety and effectiveness of the DEKA arm system during the completion of predefined tasks and spontaneous activities in both the laboratory and home settings.

However, from the studies provided, only 1 subject was a bilateral amputee with a transhumeral and a scapulothoracic level of amputation. There is concern that this group may not be able to fully utilize all safety features provided and may, therefore, be at a higher potential risk in the absence of further testing. Therefore, the safety and effectiveness of the device has not been demonstrated in bilateral amputees with a unilateral or bilateral transhumeral or scapulothoracic level of amputation.

LABELING

Patient labeling was written in accordance to the "Guidance on Medical Device Patient Labeling" (issued on April 19, 2001) and is readable and understandable. The definitions of the symbols used are described in the beginning of the User Guide. In addition, labeling was checked according to IEC 60601-1:2005 Clause 7.

The Indications for Use are located in the User and Prosthetist guides. The contraindications in the Prosthetists Guide are general to the device and appropriate.

The User/Prosthetist Guides give clear and understandable instructions to the user and prosthetist with appropriate warnings.

Contact information was also provided for replacing electrodes.

RISKS TO HEALTH

Table 4 below identifies the risks to health that may be associated with use of the DEKA Arm and the measures recommended to mitigate these risks.

Table 4 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Unintended Motion	Electronic Input Testing Software Verification, Validation and Hazards Analysis Wireless Testing Electromagnetic Compatibility (EMC) Testing Non-clinical Performance Testing Water/Particle Ingress Testing Durability Testing Battery Testing Labeling
Adverse Tissue Reaction	Biocompatibility Assessment
Battery Failure	Battery Testing Water/Particle Ingress Testing Labeling
Electromagnetic Incompatibility	EMC testing Labeling
Electrical Safety Issues	Electrical Safety Testing Labeling
Gripping Malfunction	Non-clinical Performance Testing Software Verification, Validation and Hazards Analysis Labeling
High Risk Activities (e.g., driving)	Labeling
Malfunction Due to Environmental Conditions	Non-clinical Performance Testing Battery Testing Water/Particle Ingress Testing Wireless Testing EMC Testing Flammability Testing Labeling
Use Error	Clinical Studies Human Factors Studies Labeling

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components is subject to the following special controls:

1. Appropriate analysis/testing must validate electronic compatibility (EMC), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

2. Appropriate software verification, validation, and hazard analysis must be performed.

3. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

    a. Mechanical bench data, including durability testing, to demonstrate that the device will withstand forces, conditions and environments encountered during use.
    b. Simulated use testing to demonstrate performance of arm commands and available safeguard(s) under worst case conditions and after durability testing.
    c. Verification and validation of force sensors and hand release button, if applicable, are necessary.
    d. Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor and brake performance.
    e. The accuracy of the device features and safeguards.

4. Non-clinical and clinical performance testing must demonstrate the accuracy of device features and safeguards.

5. Elements of the device that may contact the patient must be demonstrated to be biocompatible.

6. Documented clinical experience and human factors testing must demonstrate safe and effective use, capture any adverse events observed during clinical use and demonstrate the accuracy of device features and safeguards.

7. Labeling for the Prosthetist and User Guide must include:

    a. appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities that may put the user at greater risk (e.g., driving).
    b. specific instructions and the clinical training needed for the safe use of the device, which includes:
        i. instructions on assembling the device in all available configurations,
        ii. instructions on fitting the patient,

        iii.   instructions and explanations of all available programs and how to program the device,

        iv.   instructions and explanation of all controls, input, and outputs,

        v.   instructions on all available modes or states of the device,

        vi.   instructions on all safety features of the device, and

        vii.   instructions for maintaining the device.

    c. information on the patient population for which the device has been demonstrated to be effective.

    d. a detailed summary of the non-clinical and clinical testing pertinent to use of the device.

BENEFIT/RISK DETERMINATION

The risks of the device are based on non-clinical data as well as data collected from clinical studies described above. The probable risks of abrasions, heat rash, bruising, and blisters with use of the DEKA Arm are the same as other upper extremity prostheses. Additionally, the user may injure themselves or a bystander due to a device malfunction during normal use or while performing higher risk activities (e.g., holding sharp or heavy objects).

The probable benefits of the DEKA Arm System are also based on non-clinical data as well as data collected from clinical studies described above. The probable benefit of the device is the ability to complete some Activities of Daily Living (ADLs) that cannot be completed with currently available prostheses such as hammering, manipulating a door knob, using utensils, don/doff a shirt, and brushing hair and teeth.

While benefit of the device was demonstrated, there were concerns identified in the studies about the reliability of the device. Additionally, the results were primarily on unilateral amputees, and the generalization of the results to all bilateral amputees was inadequate due to concerns with their ability to use the safety features.

In conclusion, given the available information above, the data support that the use of the DEKA Arm to assist with ADLs, and the probable benefits outweigh the probable risks. The device provides benefits, and the risks may be mitigated by the use of general and special controls.

CONCLUSION

The *de novo* request for the DEKA Arm is granted and the device is classified under the following:

    Product Code: PAE

    Device Type: Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components

    Class: II

    Regulation: 21 CFR 890.3450