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

May 9, 2014

DEKA Integrated Solutions Corporation
Roger A. Leroux
340 Commercial Street
Manchester, NH 03101

Re: K121215
DEKA Arm System
Evaluation of Automatic Class III Designation - *De Novo* Request
Regulation Number: 21 CFR 890.3450
Regulation Name: 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
Regulatory Classification: Class II
Product Code: PAE
Dated: June 14, 2012
Received: June 15, 2012

Dear Mr. Leroux:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the DEKA Arm System, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> "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)."

FDA concludes that this device should be classified into class II. This order, therefore, classifies the DEKA Arm System, and substantially equivalent devices of this generic type, into class II under the generic name, 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.

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.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 18, 2012 automatically classifying the DEKA Arm System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On June 15, 2012, FDA received your *de novo* requesting classification of the DEKA Arm System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the DEKA Arm System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the DEKA Arm System indicated for the following:

> 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).

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – 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 (e.g., shock)	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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on 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 they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request 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.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Patrick Axtell, Ph.D. at 301-796-6462.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health

Concurrence & Template History Page
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Full Submission Number: K121215

Digital Signature Concurrence Table	
Reviewer Sign-Off	Patrick Axtell May 6, 2014
Branch Chief Sign-Off	Michael Hoffmann May 6, 2014
Division Sign-Off	Carlos Pena May 7, 2014
Office Sign-Off	Jonette R. Foy -S 2014.05.09 10:29:13 -04'00'

Template Name: 1a – Order Granting the De Novo

Template History:

Date of Update	Updated By	Description of Update
10/26/2012	MMJ	Updated language to align with FDASIA. Placed in Digital Signature format.
11/27/2012	MMJ	Updated sig block to show Joni Foy's new title.
12/4/2012	MMJ	Updated Digital Signature table to add a block for Office-level signoff.
12/12/2012	MMJ	One digit was missing from 4-digit ZIP code extension in letterhead ("002" should read "0002"). Revised to fix this.
1/29/2014	MMJ	Revised to reflect OCC's recent feedback to OIR on recommended content for letters granting de novos, and to add some more minor edits provided by Joni Foy.
1/31/2014	MMJ	Added paragraph regarding compliance w/other requirements of the Act.
3/4/2014	MMJ	1st full paragraph on page 2, titled"[If Class II, choose this paragraph 2]:" Changed 1st sentence from "In addition to…" to "In combination with…"