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

January 18, 2017

Iowa Adaptive Technologies, Inc. Dba Voxello, Inc.
R. Rives Bird
CEO
2500 Crosspark Road
Ste W150
Coralville, Iowa 52241

Re: K162817
Trade/Device Name: Noddle™
Regulation Number: 21 CFR 890.3710
Regulation Name: Powered Communication System
Regulatory Class: Class II
Product Code: ILQ
Dated: October 3, 2016
Received: October 6, 2016

Dear R. Rives Bird:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -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 below.

510(k) Number *(if known)*
K162817

Device Name
Noddle™

Indications for Use *(Describe)*
The Noddle™ is indicated for use by patients who have physical limitations, weaknesses, and/or limited communication abilities in order to assist them with summoning and communicating with their caregiver by controlling other devices such as the nurse call and speech generation devices. To use the Noddle™ patients should be sufficiently cognitively intact so that they can produce intentional gestures and intend to communicate with caregivers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Company Name:	Voxello
Address:	2500 Crosspark Road Coralville, IA 52241
Telephone No:	319-214-3023
Registration No.:	N/A
Contact person:	R. Rives Bird
Date Prepared:	29 November 2016
Device (trade) name:	Noddle™
Common/usual name:	Powered communication device
Classification Name:	System, communication, powered
Classification Panel:	Physical Medicine
CFR Section:	890.3710
Device Class:	Class II
Device Code:	ILQ

Predicate device:

- Substantially equivalent to Comfort Keyboard (K930044)

Device description:

The Voxello *noddle™* is a patient assistive communication device that accepts signals from a sensor to determine when a disabled patient is attempting to intentionally gesture for control of a device or system. The Voxello *noddle™* interprets the signals from the sensor to allow the user to control up to three output switches. These outputs may be connected via hardwire or Bluetooth connection to control or access devices such as nurse call stations, and/or speech generation devices.

Intended use:

The noddle™ is intended to be used by patients who cannot either access a standard nurse call and/or communicate traditionally. The noddle™ is used for alternate access to a nurse call and/or access to assistive and augmentative communication devices (speech generation devices) to communicate with caregivers.

Indications for use:

The noddle™ is indicated for use by patients who have physical limitations, weaknesses and/or limited communication abilities in order to assist them with summoning and communicating with their caregiver by controlling other devices such as the nurse call and speech generation devices. To use the noddle™ patients should be sufficiently cognitively intact so that they can produce intentional gestures and intend to communicate with caregivers.

Comparison with Predicate Device:

- It is the opinion of Voxello, that the *noddle™* is similar to the Comfort Keyboard. Both devices are used to increase access to control another, or multiple devices.

Substantial Equivalence:

The Voxello noddle™ is substantially equivalent to the commercially available Comfort Keyboard. These devices assist the patient in communicating and have similar characteristics.

Safety information:

- The Voxello noddle™ complies with all relevant EN/IEC 60601-1 Safety Standards, Particular and Collateral Standards, including the following:

AAMI ES60601-1 *BEI Issued: 2006/03/09 (R2012) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Amd. C1: 2009, Amd. 2:2010

CSA C22.2#60601-1 *DEI Issued: 2014/03/01 Ed: 3 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1:2005 Ed.3+A1;C1:2014 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2 Issued 2007/03/02 Ed: 3.0 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance; - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

ISO 14971 Issued: 2007/10/01 Ed:2 Medical Devices – Application of Risk Management to Medical Devices

Conclusion:

The Voxello *noddle™* does not introduce any new indications for use, nor does the use of the systems result in any new potential hazard. Voxello believes the *noddle™* to be substantially equivalent with the predicate device with respect to safety and effectiveness.