October 24, 2023

Edwards Lifesciences, LLC
Anna Hwang; Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K230919
Trade/Device Name: Acumen IQ finger cuff
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 31, 2023
Received: April 3, 2023

Dear Anna Hwang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230919

Device Name
Acumen IQ finger cuff

Indications for Use *(Describe)*
The Acumen™ IQ finger cuff is indicated for patients over 18 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with the HemoSphere advanced monitoring platform.

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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Acumen IQ™ finger cuff 510(k) Summary		
510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Contact Person	**Primary Contact** Anna Hwang Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250-0902 Fax: (949) 809-7303 Email: Anna_Hwang@edwards.com	**Secondary Contact** Karen O'Leary Sr. Director, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 610-9179 Fax: (949) 809 - 2954 Email: Karen_OLeary@edwards.com
Date Prepared	March 31, 2023	
Trade Name	Acumen IQ finger cuff	
Common Name	System, measurement, blood-pressure, non-invasive	
Regulation Number / Regulation Name	21 CFR 870.1130 / Non-Invasive Blood Pressure Measurement	
Product Code	DXN	
Regulation Class	Class II	
Predicate Device	K190130 - Acumen IQ finger cuff (cleared June 21, 2019)	
Device Description	The Acumen IQ finger cuff is intended to noninvasively measure blood pressure and use the information to derive hemodynamic parameters when connected to an Edwards' HemoSphere Advanced Monitoring platform.	
Indications for Use	The Acumen IQ finger cuff is indicated for patients over 18 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with the HemoSphere Advanced Monitoring Platform.	
Intended Use	The intended purpose is to noninvasively measure blood pressure and use the information to derive hemodynamic parameters when connected to the HemoSphere Advanced Monitoring Platform.	
Comparison to Predicate Device	The subject Acumen IQ finger cuff is being modified to expand the finger circumference size range from 51 - 60 mm to 43 - 71 mm as well as removal of the finger sizing aid from the packaging. There are	

Acumen IQ™ finger cuff 510(k) Summary	
	no changes to the physical design of the finger cuff, its components, dimensional features, or materials of construct.
Device Testing	The subject Acumen IQ finger cuff is identical to the predicate device in terms of design, intended use and technology. To ensure that the size range extension and removal of the sizing aid do not raise any new concerns of safety and effectiveness and are substantially equivalent to the predicate device, usability testing was conducted in accordance with ANSI/AAMI HE75. Furthermore, clinical performance testing was completed to ensure the finger cuffs perform as intended. The Acumen IQ finger cuff has successfully passed all testing.
Conclusion	The subject Acumen IQ finger cuff is substantially equivalent to the predicate device.