(6) Software verification, validation, and hazard analysis must be performed.

(7) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the identified shelf life.

(8) Human factors testing and analysis must validate that the device design and labeling are sufficient for the end user.

(9) Physician labeling must include:

(i) The operating parameters, name, and model number of the indicated external dosage controller;

(ii) Information on how the device operates and the typical course of treatment;

(iii) Information on the population for which the device has been demonstrated to be effective;

(iv) A detailed summary of the device technical parameters; and

(v) Provisions for choosing an appropriate size implant that would be exchanged for the tissue expander.

(10) Patient labeling must include:

(i) Warnings, precautions, and contraindications, and adverse events/complications;

(ii) Information on how the device operates and the typical course of treatment;

(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-operative care instructions; and

(v) Alternative treatments.

(11) Patient training must include instructions for device use, when it may be necessary to contact a physician, and cautionary measures to take when the device is implanted.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02357 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2021–N–0998]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Alternate Controller Enabled Infusion Pump

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the alternate controller enabled infusion pump into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the alternate controller enabled infusion pump's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES:

Effective date: This order is effective February 4, 2022.

Applicability date: The classification was applicable on February 14, 2019.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the alternate controller enabled infusion pump as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 29, 2018, FDA received Tandem Diabetes Care, Inc.'s request for De Novo classification of the t:slim X2

insulin pump with interoperable technology. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the generals controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 14, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 880.5730.[1] We have named the generic type of device ''alternate controller enabled infusion pump,'' and it is identified as an alternate controller enabled infusion pump (ACE pump). The ACE pump is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected devices for the purpose of drug delivery.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ALTERNATE CONTROLLER ENABLED INFUSION PUMP RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Patient harm due to inadequate drug delivery accuracy that leads to over infusion or under infusion of drug.	Basal and bolus drug delivery accuracy validation testing, Device use life reliability testing, Design mitigations to prevent cross-channeling. Validated and traceable risk control measures for identified hazards.
Patient harm due to undetected pump occlusions that pose risk of under infusion of drug.	Hazard detection (*e.g.,* drug occlusion) validation testing.
Patient harm due to incompatibility between the drug and the pump that may lead to over infusion or under infusion of drug, or exposure to harmful substances leached from pump materials into the infused drug solution.	Drug compatibility testing.
Inability to provide appropriate treatment due to loss of communication with digitally connected alternate pump controller devices.	Validated communication specifications, processes, and procedures with digitally connected devices.
Commands from the digitally connected alternate pump controller devices that conflict with existing pump commands may lead to unintended over or under infusion of drug.	Validated communication specifications, processes, and procedures with digitally connected devices, Validated failsafe design features.
Conflicting interfaces resulting in over or under delivery	Validated communication specifications, processes, and procedures with digitally connected devices, Validated failsafe design features.
Patient harm due to insecure transmission of data	Validated communication specifications, processes, and procedures with digitally connected devices.
Patient harm due to inability to determine source of dosing error when used in an integrated system.	Validated data logging capability.
Patient harm due to exposure to hazardous and non-biocompatible materials or pathogens.	Biocompatibility testing, Validation of reprocessing procedures.
Patient harm due to data transmission interference/electromagnetic disturbance.	Electrical safety, electromagnetic compatibility, and radio frequency wireless safety testing.
Patient harm due to incorrect use of pump, operational, and/or use-related errors.	Human Factors testing, Transparent pump performance descriptions in labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 880.5730 to subpart F to read as follows:

§ 880.5730 Alternate controller enabled infusion pump.

(a) *Identification.* An alternate controller enabled infusion pump (ACE pump) is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include the following:

(i) Evidence demonstrating that device infusion delivery accuracy conforms to defined user needs and intended uses and is validated to support safe use under actual use conditions.

(A) Design input requirements must include delivery accuracy specifications under reasonably foreseeable use conditions, including ambient temperature changes, pressure changes (*e.g.,* head-height, backpressure, atmospheric), and, as appropriate, different drug fluidic properties.

(B) Test results must demonstrate that the device meets the design input requirements for delivery accuracy under use conditions for the programmable range of delivery rates and volumes. Testing shall be conducted with a statistically valid number of devices to account for variation between devices.

(ii) Validation testing results demonstrating the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (*e.g.,* occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes. Hazard detection must be appropriate for the intended use of the device and testing must validate appropriate performance under the conditions of use for the device.

(iii) Validation testing results demonstrating compatibility with drugs that may be used with the pump based on its labeling. Testing must include assessment of drug stability under reasonably foreseeable use conditions that may affect drug stability (*e.g.,* temperature, light exposure, or other factors as needed).

(iv) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible. This shall include chemical and particulate characterization on the final, finished, fluid contacting device components demonstrating that risk of harm from device-related residues is reasonably low.

(v) Evidence verifying and validating that the device is reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.

(vi) The device must be designed and tested for electrical safety, electromagnetic compatibility, and radio frequency wireless safety and availability consistent with patient safety requirements in the intended use environment.

(vii) For any device that is capable of delivering more than one drug, the risk of cross-channeling drugs must be adequately mitigated.

(viii) For any devices intended for multiple patient use, testing must demonstrate validation of reprocessing procedures and include verification that the device meets all functional and performance requirements after reprocessing.

(2) Design verification and validation activities must include appropriate design inputs and design outputs that are essential for the proper functioning of the device that have been documented and include the following:

(i) Risk control measures shall be implemented to address device system hazards and the design decisions related to how the risk control measures impact essential performance shall be documented.

(ii) A traceability analysis demonstrating that all hazards are adequately controlled and that all controls have been validated in the final device design.

(3) The device shall include validated interface specifications for digitally connected devices. These interface specifications shall, at a minimum, provide for the following:

(i) Secure authentication (pairing) to external devices.

(ii) Secure, accurate, and reliable means of data transmission between the pump and connected devices.

(iii) Sharing of necessary state information between the pump and any digitally connected alternate controllers (*e.g.,* battery level, reservoir level, pump status, error conditions).

(iv) Ensuring that the pump continues to operate safely when data is received in a manner outside the bounds of the parameters specified.

(v) A detailed process and procedure for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.

(4) The device must include appropriate measures to ensure that safe therapy is maintained when communications with digitally connected alternate controller devices is interrupted, lost, or re-established after an interruption (*e.g.,* reverting to a pre-programmed, safe drug delivery rate). Validation testing results must demonstrate that critical events that occur during a loss of communications (*e.g.,* commands, device malfunctions, occlusions, etc.) are handled appropriately during and after the interruption.

(5) The device design must ensure that a record of critical events is stored and accessible for an adequate period to allow for auditing of communications between digitally connected devices and to facilitate the sharing of pertinent information with the responsible parties for those connected devices. Critical events to be stored by the system must, at a minimum, include:

(i) A record of all drug delivery

(ii) Commands issued to the pump and pump confirmations

(iii) Device malfunctions

(iv) Alarms and alerts and associated acknowledgements

(v) Connectivity events (*e.g.,* establishment or loss of communications)

(6) Design verification and validation must include results obtained through a

human factors study that demonstrates that an intended user can safely use the device for its intended use.

(7) Device labeling must include the following:

(i) A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate.

(ii) A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.

(iii) A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: Number of bolus doses with volume that is <25 percent, 25 percent to <75 percent, 75 percent to <95 percent, 95 percent to <105 percent, 105 percent to <125 percent, 125 percent to <175 percent, 175 to 250 percent, and >250 percent of the commanded amount.

(iv) A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warmup period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on the drug delivered) may be provided as follows, as applicable: The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point.

(v) A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps.

(vi) For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.

(vii) For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02369 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ97

Informed Consent and Advance Directives

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) published an interim final rule amending its regulation regarding informed consent and advance directives. In that rulemaking, we amended the regulation by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. Before adopting that interim final rule as final, VA revises the provision related to which personnel may be delegated the responsibility for providing a patient with information needed for the patient to make a fully informed consent decision. Upon further review, VA has determined that this provision requires a further change to better clarify roles in the team-based delivery of care model. We are providing the public an opportunity to submit comments solely on this amendment.

DATES:

Effective date: This interim final rule is effective February 4, 2022.

Comments due date: Comments must be received on or before April 5, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Lucinda Potter, LSW, Acting Director of Ethics Policy, National Center for Ethics in Health Care (10ETH), Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; 484–678–5150. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In an interim final rule published May 27, 2020 (85 FR 31690), we amended 38 CFR 17.32, our regulation addressing informed consent for treatments and procedures, by reorganizing it and amending language where necessary to enhance clarity. We also made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witnessing for a VA Advance Directive. We amended the definition of ''practitioner'' to include other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

Under the previous informed consent rule, the practitioner, who had primary responsibility for the patient or who would perform the particular procedure or provide the treatment, was responsible for explaining in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. There was no provision in the rule addressing the question of whether, consistent with a team-based delivery of care model, appropriately trained health care team members had a role in the informed consent process. In the May 2020 interim final rule, we dealt with that issue in paragraph (c)(6), stating that the practitioner may delegate to other trained personnel responsibility for providing the patient with clinical information needed for the patient to make a fully informed consent decision but must personally verify with the patient that the patient has been appropriately informed and voluntarily consents to the treatment or procedure.

VA intended that paragraph (c)(6) give the practitioner discretion to more fully utilize the training and expertise of non-practitioners within the bounds of the