Appendix B –Classification of Medical Devices

This appendix explains the classes for medical devices and the petition to reclassify a device.

Classification of devices by the FDA is a central requirement of the Medical Device Amendments of 1976. Three "classes" are defined in the law. They are the following:

Class I – General Controls

Class II – Special Controls (originally Performance Standards)

Class III – Premarket Approval.

The primary definitions for the classes are contained in the law at 21 U.S. Code § 360c - Classification of devices intended for human use. As written, these definitions are quite involved because they reference other sections of the law.

Definitions in the Law

(a)CLASSES OF DEVICES
(1) There are established the following classes of devices intended for human use:
(A)Class I, General Controls.—
(i)
A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii)A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—
(I)
is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
(II)
does not present a potential unreasonable risk of illness or injury,
is to be regulated by the controls referred to in clause (i).

(B)Class II, Special Controls.—
A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including

the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C)Class III, Premarket Approval.—A device which because—

(i)

it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)

(I)

is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II)

presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

Definitions in the Regulations

The FDA created alternative definitions in the regulations which are easier to understand, because they provide hints to the contents of the cited sections, e.g., section 351 of the medical device amendments (the law) is section 501 of the code of federal regulations, which deals with "adulteration".

The definitions of the device classes is located at 21 CFR 860.3. (This is the abbreviation of "title 21 of the Code of Federal Regulations Part 860.)

(c) "Class" means one of the three categories of regulatory control for medical devices, defined below:

(1) *Class I* means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification

and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury.

(2) *Class II* means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(3) *Class III* means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

As you can see, the requirements for devices in the lowest class are not trivial. Not obvious in the list of requirements under Class I are "Good Manufacturing Practices" which are extensive.

There are provisions by which devices can be exempted from one or more of the requirements of Class I.

PETITIONS TO RECLASSIFY

The latest up-to-date regulations can be found at the electronic code of federal regulations: https://www.ecfr.gov

As of November 21, 2018, the requirements for a petition to reclassify a device are as follows:

§860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., “It is requested that _ device(s) be reclassified from class III to a class II”;

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of §860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

Comment: As noted above, both a completed supplemental data sheet (Form FDA 3427) and a completed classification questionnaire (Form FDA 3429) must be included in a petition to reclassify.