

POSITION STATEMENT

PRESSURE REGULATORS, CYLINDER VALVES, AND CYLINDERS WITH VALVES AS MEDICAL DEVICES

Purpose

This position statement provides the Compressed Gas Association (CGA) rationale for:

- not considering cylinders with plain valves as medical devices; and
- considering valve integrated pressure regulators (VIPRs) the same as standalone pressure regulators utilizing product code CAN and for eliminating product code ECX.

Background

Compressed gas industry medical device manufacturers have utilized both ECX (Cylinder, compressed gas, and valve Class 1, 510(k) now required) and CAN (Regulator, pressure, gas cylinder, Class 1, 510(k) exempt) product codes when classifying their VIPR devices and systems. The U.S. Food and Drug Administration (FDA) classification of VIPR devices and systems within product code ECX was inconsistent until the FDA appeared to reclassify all previously cleared ECX devices (some of which were “unclassified” and one which was Class II) to Class I in 2016.

While this action resolved the compressed gas industry’s confusion regarding classification, a discrepancy is still present within the ECX product code definition. The FDA lists the submission type for ECX as 510(k) required while identifying the applicable regulation as Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 868.2700 “Pressure Regulator”, which is exempt from pre-market notification and states the following [1]:

- *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.
- *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

Question

Should cylinders with plain valves be classified as medical devices?

Answer

No. The U.S. Department of Transportation (DOT), in Title 49 of the U.S. *Code of Federal Regulations* (49 CFR) Part 171.8 “Definitions and Abbreviations”, defines packaging to mean “a receptacle and any other components or materials necessary for the receptacle to perform its containment function in conformance with the minimum packing requirements of this subchapter” [2]. Parts 178.1 to 178.3 of 49 CFR describe packaging and containers used for the transportation of hazardous materials such as compressed gases, in commerce. Cylinders in compliance with DOT specifications (including UN cylinders and special permit requirements) are included in these sections. CGA interprets this to mean that a cylinder and a valve are components of a package, and a cylinder with an installed valve is a package used for transportation and therefore is not a medical device.

Furthermore, plain valves do not regulate pressure or flow, but rather only open and close the container that may or may not contain pressure. FDA’s Center for Drug Evaluation and Research (CDER) considers, and for over a half century has considered, medical gas cylinders and valves as drug product containers and closures. Therefore, cylinders with plain valves should not be medical devices.

Question

Should a VIPR paired with a cylinder be considered a separate device from a VIPR that is not paired?

Answer

No. The VIPR is a medical device, the functionality of which is only contingent on its design not on its pairing with a cylinder. Unlike simply opening and closing, as a plain valve does, a VIPR's primary function, like other stand-alone pressure regulators with product code CAN, is to regulate the gas pressure down from the high pressure contained in the cylinder to a designed usable service pressure. The VIPR design may include a means to use this service pressure to provide a specified flow. Currently some VIPRs are classified as CAN and others are classified as ECX, even though their functionality is the same and the physical devices are indistinguishable from each other.

Question

Are CAN and ECX product codes both required for VIPRs, and if not, which product code should be used?

Answer

No, both product codes, CAN and ECX, are not required. VIPRs should utilize product code CAN. The FDA has recently reclassified ECX as Class 1 and identified pressure regulator regulation in 21 CFR Part 868.2700 as applicable. Although CGA sees this as a positive step, 21 CFR Part 868.2700 is the same regulation identified for the CAN product code utilized for all other pressure regulators. Because VIPRs currently classified as ECX are functionally, and from a regulatory basis, identical to those classified as CAN, they can all be classified in accordance with historic practice for regulators, as CAN without compromising patient and end user safety. Therefore, CGA proposes the elimination of the ECX product code to simplify the regulation, to reduce burden on manufacturers, and to improve the uniformity of compliance across the industry.

The industry agrees that a 510(k) is not required as explicitly stated in 21 CFR Part 868.2700(b) currently cited by both the ECX and CAN product codes.

Question

How does the use of only one product code, specifically CAN, clarify regulatory responsibilities for manufacturers?

Answer

Utilizing only the CAN product code will eliminate the following confusion as to who the device manufacturer is:

- A firm that initially installs VIPRs in cylinders or reinstalls VIPRs after periodic cylinder requalification would not be considered a device manufacturer;
- A firm that fills cylinders equipped with VIPRs and performs periodic inspections in accordance with the manufacturers requirements would not be considered a device manufacturer; and
- A firm that applies post manufacture labeling may not need to register as a medical device manufacturer unless that firm is the specification developer. Note, these specification developers use contract manufacturers to actually manufacture the VIPR.

Regarding the regulatory requirements for a unique device identifier (UDI), utilizing only the CAN product code clarifies the need to mark only the VIPR heads with the UDI and not their attached cylinders or the paired system. This also eliminates inconsistent UDI labeling when a VIPR-cylinder pair is separated during mandatory DOT requalification of the cylinder. There would be no need to maintain a VIPR-cylinder pairing after requalification, nor a need to re-label a new pairing.

Conclusion

In reviewing the current registrations under the CAN and ECX product codes in light of the evidence presented in the position statement, CGA recommends the FDA eliminate the ECX product code and standardize the product code for medical gas regulators as CAN. This step would eliminate confusion for device manufacturers, gas