

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.