Is The Medical Gas A Drug Or Device?

Some medical gases are clearly drugs (e.g. oxygen used for breathing). Some medical gases are clearly devices (e.g. clinical blood gas mixtures). Some medical gases can be either a drug or device depending on their application (5 % carbon dioxide; 95 % oxygen mixture).

The FDA regulates the manufacturing of drug gases and device gases with separate regulations:

- Drugs – Current Good Manufacturing Practices – 21 CFR Part 210 and Part 211, etc.
- Devices – Quality System Requirements – 21 CFR Part 820, etc.

Some of the drug regulations are very similar to device regulations. However, there are also significant differences in the regulations (labeling, registration, etc.). It is critical for medical gas manufacturers to apply the appropriate regulations to the production of the gas.

So, how are we to know if the medical gas is a drug or device? The key element is the "intended use" (see below). It is important to note that FDA considers the manufacturer of the drug to be responsible for determining and labeling the "intended use". See "Appendix 1 – Intended Use Regulation", below for the full text of the regulation. Since the customer typically knows the intended use we advise you to ask the customer whether they want a drug gas or a device gas. Then, you produce the gas in accordance with the applicable regulations (drug or device).

What is a Drug? See "Appendix 2 – Drug and Device Definitions" for the full text.
According to 21 USC 301 Section 201(g)(1), a drug is:

- Recognized in USP/NF or other compendia
- Intended to diagnose, cure, mitigate, treat or prevent disease
- Intended to affect structure or function
- Intended as component of the items above
- There are exceptions for foods and food supplements

What is a Device?
According to 21 USC 301 Section 201(h), a device is Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or component:

- Recognized in USP/NF or other compendia
- Intended for use in diagnosis of disease or other conditions
- Intended for use in the cure, mitigation, treatment, or prevention of disease
- Intended to affect structure or function

The device definition excludes:

- Products that achieve their primary intended purpose through chemical action within or on the body
- Products that are dependent upon being metabolized for the achievement of their primary intended purpose

Appendix 1 – Intended Use Regulation

[Code of Federal Regulations]
[Revised as of April 1, 2010]
TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 201_LABELING--Table of Contents
Subpart D_Exemptions From Adequate Directions for Use

Sec. 201.128 Meaning of ``intended uses".

The words intended uses or words of similar import in Sec. Sec. 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

Appendix 2 – Drug and Device Definitions

Federal Food, Drug, and Cosmetic Act (FD&C Act) *(emphasis and formatting added)*
SEC. 201. [21 U.S.C. 321]
CHAPTER II—DEFINITIONS 1
SEC. 201. [21 U.S.C. 321] Definitions; generally

(g)(1) The term **"drug"** means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(h) The term **"device"** (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.