THE FDA & EMERGENCY RESPONSE EQUIPMENT

BY ALEX STENZLER

When purchasing medical devices, waterpark operators need to ensure products are FDA compliant.

THE FOOD AND DRUG Administration's Center for Devices and Radiological Health (CDRH) is the agency responsible for the clearance and listing of all medical devices sold or used in the United States. It is important for those in the waterpark and aquatics industry to understand this oversight, review their decision-making processes and determine how these factors impact their selection of medical devices required for operational use.

UNDERSTANDING THE FDA AND RESCUE EQUIPMENT

Many owners and managers of waterparks don't fully understand that there are FDA requirements for every rescue device or supply they purchase. While waterparks are not medical facilities, much of the equipment purchased for rescue uses are medical devices that fall under the purview of the FDA. This equipment includes AED units, bag valve masks, all oxygen equipment, pocket masks, resuscitation valves, cervical collars and suction equipment. Even adhesive bandages are listed by the FDA.

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FDA CLASSIFICATIONS AND CLEARANCE FOR SALE

The FDA has three classifications of medical devices. These are:

- **CLASS 1** (usually low risk devices that require general manufacturing controls and are listed with the FDA)
- **CLASS 2** (held to a higher level of scrutiny and usually requires submission to the FDA for evaluation of meeting performance standards, labeling, safety and post-market surveillance)
- **CLASS 3** (higher risk devices that usually sustain or support human life and require clinical trials to assure safety and efficacy).

However, every device, no matter what the class, is required to be either listed with the FDA (Class 1) or reviewed by the FDA, with a 510(k) clearance letter issued (Classes 2 and 3). Trained waterpark personnel should confirm that all medical equipment being considered for purchase has met these minimum FDA requirements. Any failure of a rescue device that has not been FDA listed or reviewed (510(k)) places excessive liability on the waterpark, potentially invalidating insurance claims.

So, how does a waterpark know if a product purchased is FDA listed or has a 510(k)?

Rescue product suppliers should be able to provide copies of the 510(k) or a copy of the listing for the products they sell to the waterpark. If they are not available, the FDA has a web page where the recording of the product should be found: *(See Figure 1 to see a sample of the searchable database form.)*

1. Go to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm.
2. On that page there is a box for the product code.
3. Enter the code from the table shown in Figure 2.
4. All recorded suppliers of cleared products are listed.

Products that are not recorded on the FDA website should not be considered for purchase.

LABELING REQUIREMENT FOR PRESCRIPTIONS

Another area of uncertainty for waterparks is labeling on medical products stating "Caution: Federal Law restricts this device to sale by or on the order of a physician," or some equivalent statement. Many of the rescue products used in waterparks are therefore "prescription only" products, but are used without a physician ordering their use. There are reasons why this is allowed by the FDA.

In 1996, the FDA sent a letter to the U.S. Com-

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FIGURE 1

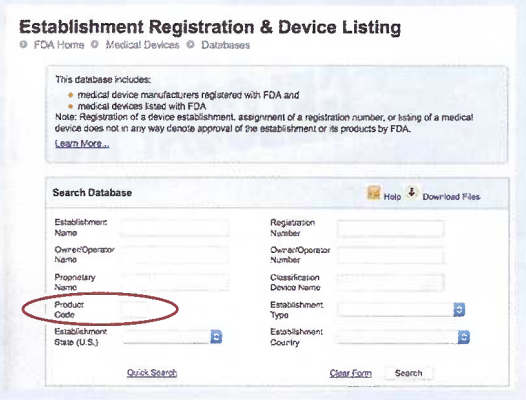

FIGURE 2

Description	(Class)	Product Code	Description	(Class)	Product Code
Ventilation Masks	(1)	BSJ	Non-Rebreather O2 Masks	(1)	KGB
Bag Valve Masks	(2)	BTM	Oxygen Masks	(1)	BYG
Resuscitation Valves	(2)	CBP	Oxygen Regulators	(1)	CAN
Defibrillators	(3)	MKJ	Oxygen Cylinders	(1)	ECX
Suction Devices	(1)	GCY	Cervical Collars	(1)	IQK

Note: Sometimes manufacturers incorrectly list their products so that all mask Product Codes may need to be reviewed to find a specific product. All Class 2 and 3 devices require a 510(k).

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pressed Gas Association stating that labeling for oxygen and its delivery systems should include the statement, *"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."*

In 1997, an FDA Guidance Document was released that stated, "Oxygen generators and oxygen equipment intended for emergency use may be marketed for over-the-counter (OTC) distribution" as long as they "don't contain references to heart attacks, strokes, shock or any other medical condition which only licensed practitioners diagnose or treat."

This guidance document created a pass for waterparks to purchase and use most rescue equipment without the requirement for a physician's prescription. Examples of these products include, but are not limited to, emergency oxygen, bag-valve resuscitators, ventilation mask kits and resuscitation valves, all of which are widely used in the aquatics industry.

In 2016, the FDA issued an alert regarding small oxygen devices that do not meet the requirements of the previous guidance document. Again in that 2016 alert, the FDA reiterated that, "The Food and Drug Administration generally regards oxygen to be a prescription drug. Nevertheless, FDA recognizes that there are many circumstances under which it would be impractical to insist that oxygen be administered only under the supervision of a physician, and, "oxygen units may be marketed without a prescription when used for emergency resuscitation and when administered by an individual who is authorized, certified or licensed by state authorities. Such units must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes (90 liters). Labeling for emergency oxygen for OTC use may not contain references to any medical conditions, disorders or diseases."

The FDA's position is that a prescription device, such as the equipment used with supplemental oxygen, can be applied in an emergency situation without a prescription by personnel trained in its use.

CONCLUSION

Our experience in speaking with owners and managers of waterparks is that there is broad misunderstanding of the responsibility of the Food and Drug Administration. This is particularly true with regard to the requirements for approval and labeling of the devices used by the waterpark's lifeguard and emergency response teams. It is clear from the FDA regulations that all such equipment requires FDA listing or clearance for sale, and that prescriptions are not required for rescue equipment when used by trained individuals. These facts should impact the operation and decision-making processes of waterparks.

It is recommended that all owners and managers review their equipment and purchasing procedures to ensure that they protect their waterparks and their customers appropriately. •

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