HealthTech Activator

Medical Device Access to the US Market

510(K) REGULATORY REQUIREMENTS

WEARABLE DEVICE FOR OXYGEN SATURATION– CASE STUDY

OxyResp™ is a start-up company developing a wearable device that measures a person's circulating oxygen saturation. The prototype device is produced in the form of a ring to be worn on the person's finger. The device communicates with a person's laptop or smartphone via Bluetooth to make real-time recommendations for patients using supplementary oxygen.

The company has an early working prototype, but has yet to finalise some of the electronics components to further miniaturise the device. The current device is effective at taking accurate measurements and transmitting them via Bluetooth every half hour.

The limited battery storage capacity needs regular charging, currently every 24 hours. The company is working on a smaller version, but there are trade-offs to be made between battery life and how frequently measurements can be taken in the smaller device. The miniaturised device would only take and transmit a measurement every four hours and would have no digital screen on the ring itself, relying on the paired smartphone or computer for the user interface.

The company may need to revert to a bracelet-sized device if the regulatory pathway of the miniaturised ring doesn't look promising.

Components of the device include:

- Light source and light meter (red and infrared spectrum)
- Lithium ion cell
- Pressure sensor switch (on/off switch)
- Embedded software and circuitry within ring
- Digital screen
- Bluetooth transmitter
- Induction charging
- Software for installation on mobile phone or computer to pair with device for control and sharing readings (patient user interface)
- Software for installation on doctor's computer that provides monitoring data.

POWERED BY
CallaghanInnovation
New Zealand's Innovation Agency

HealthTech Activator

The device is intended to be prescribed for people with severe respiratory disease (emphysema) to recommend when the person should start using supplemental oxygen, for titrating dosage and advising when to stop the oxygen. It will be used in a home or aged care facility setting where supplemental oxygen is already available and has been prescribed by a doctor. There are established guidelines for oxygen use that the device will help patients adhere to[1], while providing data to their doctor about how well their respiratory function is controlled.

The company has hired a person with a background in Quality Assurance (while recognising the person is going to need to upskill in Regulatory Affairs), who is trying to get up to speed with the US FDA requirements for the miniaturised device. They are trying to get answers to the following questions online:

1. **What class of device is the miniaturised oxygen saturation meter in the US?**
    a. Does the device capability – to recommend starting and stopping supplemental oxygen therapy – change the classification and other aspects of the regulatory pathway?
2. **What regulatory approval process/path would the company need to follow?**
3. **Can the company change some aspects of the device once it has regulatory approval?**
    a. Specifically the company intends inserting a smaller battery; eliminating a digital screen on the ring; and reducing the frequency of oxygen saturation measurements that are recorded. Does this change any regulatory requirements?
4. **What testing is needed to generate the required data for the FDA?**

ANSWERS TO THE COMPANY'S QUESTIONS

1. **What class of device is the miniaturised oxygen saturation meter in the US?**

The proposed device can be considered to be the combination of two main clinical functions: an oxygen saturation meter and a drug (oxygen supplementation) dosage algorithm.

If market access is applied for separately, these functions would each be considered to have the following classification:

1. British Thoracic Society guidelines for home oxygen use in adults: accredited by NICE: http://thorax.bmj.com/content/70/Suppl_1/i1

- Oxygen saturation meter: Class II device (Industry Guidance document for 510(k)s for Pulse Oximeters[2])
- Drug dosage algorithm:
  - Where a software program simply provides medication dosage advice in electronic form that is part of a well-established clinical guideline, the FDA may use its discretion not to regulate the software[3] and define the software as a form of Clinical Decision Support (CDS).
  - Where such dosage advice, however, is not well established or is integral to a sensor device, the FDA regulates the device as a single device entity.

The device in this example would be assessed according to its overall intended use and would be eligible for the 510(k) pathway if a suitable comparator (predicate) device can be found on the US market. If a comparator device cannot be found, a 510(k) de novo regulatory process would likely apply if a moderate risk profile is established. If the management of supplemental oxygen is seen to pose an increased risk to the patient, the FDA could classify The device as Class III, although unlikely. In this case the company would need to prepare for a Premarket Approval (PMA) pathway, which requires a full review of the product and clinical evidence without reference to comparator products. Early engagement with the FDA is recommended in order to obtain agreement on the appropriate regulatory strategy for market access.

a. Does the device capability – to recommend starting and stopping supplemental oxygen therapy – change the classification and other aspects of the regulatory pathway?

Yes. This is the pivotal difference in this product that makes it different from other oxygen saturation meters (pulse oximeters) on the market. It is also this novel element of the device that poses a risk to the patient if it does not operate correctly, and the company would need to identify, quantify and manage this risk.

2. What regulatory approval process/path would the company need to follow?

The regulatory pathway for a standard oxygen saturation meter (pulse oximeter) is well defined, with a recently published Industry Guidance document available that sets out the process of gaining approval through a 510(k) process.

2. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug
3. https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf

The guidance documents also, at times, provide advice that may be commercially beneficial. In the example of oxygen saturation meters, FDA guidance includes a provision for using Original Equipment Manufacturer (OEM) components that have already been cleared by the regulator for the same intended use. Using such components would potentially allow faster or more reliable regulatory approval.

3. **Can the company change some aspects of the device once it has regulatory approval?**

The company is limited in what changes can be made to the product once it has been approved, as some changes would alter the potential effectiveness and safety profile of the device. FDA has published a guidance document for industry: 'Deciding When to Submit a 510(k) for a Change to an Existing Device'. The company should assess the type of change and what, if any, additional submission would be required.

Refer to:

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc eDocuments/ucm514771.pdf

a. Specifically the company intends to insert a smaller battery; eliminate a digital screen on the ring; and reduce the frequency of oxygen saturation measurements that are recorded. Does this change any regulatory requirements?

Where any of these changes may have an impact on the safety, performance and technology characteristics of the device, the company is responsible to perform an internal regulatory assessment to determine the significance of the changes. Depending on the outcome of the assessment, if a new 510(k) is required, the company is required to submit data to support the proposed changes as well as demonstrate substantial equivalence to a selected predicate device.

The guidance document specifies that miniaturisation is a risk and would likely need a further application to be submitted.

If the safe use of oxygen (according to the clinical guidelines being referenced) needs a certain frequency of measurement, any change to the frequency would again need a further application.

4. What testing is needed to generate the required data for the FDA?

The route to market is highly influenced by the regulatory pathway and timing of market entry for the two functions of the device. The company could choose two basic routes to market:

- Launch a simple miniaturised oxygen saturation meter first and subsequently develop evidence for the device in supporting oxygen therapy dosage.
  - Commercial advantage of early sales with easier initial regulatory approval
  - Commercial risk of delay in achieving the true market potential for the intended use in effectively managing two separate approval processes and launches.
- Launch a fully developed device with complete package of safety and effectiveness data provided to FDA.
  - Commercial advantage of being first to launch full functionality of new device
  - Commercial risk of needing a PMA and the safety or clinical effectiveness not having positive benefit/risk profile as considered by FDA evaluators.

Extract of Industry Guidance document:

'A manufacturer that wishes to seek a specific clinical indication for use of a pulse oximeter, for example to screen for or diagnose a disease or condition, should submit clinical safety and effectiveness data to support the specific indication. A clinical evaluation of a new intended use of a legally marketed device may require an Investigational Device Exemption (IDE) under 21 CFR Part 812 before the clinical study is initiated.'

For specific testing requirements of this device (and similar for others), the guidance documents provided by the FDA generally refer to testing regimes for the company to comply with, e.g. ISO 80601-2-61:2011. Additionally, ISO 11073-10 may also apply.

Guidance documents provide recommendations for the scope of testing, such as materials testing for those components that will be in patient contact for biocompatibility (ISO 10993), benchtop (as cited above) and clinical testing of the device, if required.