

# RxAir360

## NEWSLETTER

Greetings RxAir360 Family,

We are pleased to announce that our prototype is still on track to be completed, tested, and submitted to the FDA for final 510(k) clearance by the end of this year.



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clinical hyperbaric oxygen device

### The Latest

Hydrostatic testing involves filling a chamber with water and pressurizing it to a specific pressure for a set amount of time. Calibrated pressure transducers monitor the pressure, and a drop in pressure indicates a leak. Hydrostatic testing is a non-destructive method that's often used to assess the strength of pressure vessels like boilers, fuel tanks, gas cylinders, and pipelines. For example, compressed gas cylinders must be hydrostatically tested every 10 years to ensure they're safe.

### What's Next?

We are engaged with FDA 510k Consultants, LLC to help us maneuver through FDA's complex medical device pathway. With over a decade of experience, many of their consultants are former FDA employees.

Companies must file a 510(k) Premarket Notification to receive FDA "clearance" to market medium-risk medical devices. A 510(k) petition is a technical document. It is designed to demonstrate the product's safety and effectiveness.

Their goal is to assist us in clearing our medical device for the U.S. market by the end of the year.

### Validation

In our efforts to keep you informed about the latest in Hyperbaric Oxygen Therapy and its global impact, we encourage you to review the articles we have provided. These resources aim to help you better understand why we are excited and committed to offering this product in private practice physicians' examination rooms.



Former 'Jeopardy!' host Mayim Bialik receives hyperbaric chamber treatment to address health issues

[\\* Click Here](#)

Newmarket Health Wellness - HBOT Introduction Video

[\\* Click Here](#)

Benefits of Hyperbaric Chamber Therapy

[\\* Click Here](#)