Original E-mail (9/12/2021):

Hi [BreakthroughDevicesProgram@fda.hhs.gov contact],

It took me a while, but the company acknowledged that they do not have FDA approval for the product.

So, I have the following questions:

1) Does the following content need to be changed?

"***This is the same method we use in our new FDA-approved Oral and Throat Cancer Test***.".

https://www.viome.com/blog/what-makes-viome-best-gut-microbiome-testing-company

2) Since I learned about this from the first link in the forwarded e-mail, does the company need to follow-up with customers and those given incorrect information to make clear **no** products are FDA approved? I think there is also at least 1 other public example where FDA approval was at least implied (where this article references the Viome CEO describing "[this] FDA approval"). Likewise, the title for this article and this article cite FDA approval, but I am not sure why those reporters said that.

You previously informed me about the regulatory misconduct reporting system. So, if that is the best contact for these questions, I have also cc'd CDRHDeviceAllegations@fda.hhs.gov.

I have attached a subset of notes that I thought might be relevant. If you would like for me to provide any additional information, please let me know.

Thank you very much for all of your hard and important work.

Sincerely,
Charles

Additional notes:

On 7/2/2021, I received a message that initially said "*Yes, the article you see is true that we are using the same method as our new FDA-approved oral and throat cancer test. However, this is service is not available yet.*".

However, I could not see a listing for Viome in any of the databases that you described. So, on 7/26/2021, I asked if there was some sort of identifier that I could use to confirm the product was FDA approved (and if they knew which database I should use for confirmation).

I didn't receive a response to that message.

However, I went back through the messages and noticed some things that don't make sense (such a reference the Nature Biotechnology article that I mentioned, which said that product was not FDA and contradicted the other reference). I sent another e-mail message on 9/7/2021, and I received the following response:

"*Our cancer screening test does not have FDA approval. It has received FDA Breakthrough Device designation. Basically, "The FDA considers a technology worthy of breakthrough designation when it represents unparalleled innovation with no cleared alternatives, has the potential to be a more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and has the opportunity to benefit the lives of many patients.*""

In both cases, I am adding the reformatting in the red text above.