Application Information *Information de soumission*			
Application ***Soumission*** 319520	**Licence Name** ***Nom de l'homologation*** ANOSMIC COVID-19 SMELL TESTER	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument*** 1
Application Type ***Type de soumission*** Application under IO	**Licence Type** ***Type d'homologation*** Single Device	**Manufacturer** ***Fabricant*** VIROCULE INC.	**Company ID** ***No. d'entreprise*** 160784

Note to File Purpose *Objet de Note au dossier*		
Subject/*Objectif* **IO Submission –**		
Division: Science Advisor	Date Assigned: *Date assignée:* **Oct. 5, 2020**	Date Completed: *Date d'achèvement:* **Oct.**
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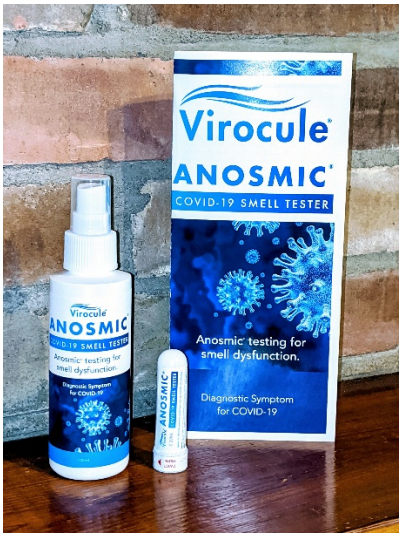
1 Background/*Antécédents*

The following information has been provided by the manufacturer.

- Virocule Pilot Clinical Trial 1 Report-Sep2020
- QPharm Site Licence
- QPharm Drug Establishment Licence
- Ansomia News 30Sep2020
- Anosmic Literature
- Anosmic Product Tester Image

The above product was classified as a medical device on July 30, 2020.



2 Evaluation/*Évaluation*

The "Anosmic COVID-l9 Smell Tester" is a non-invasive diagnostic device that is intended to detect anosmia or the loss of sense of smell owing to olfactory dysfunction caused by coronavirus in current application. Its use can be extended to other neurodegenerative disorder such as Parkinson, Alzheimer or Multiple Sclerosis.

One of the first studies using smell quantitative assessment (University of Pennsylvania Smell Identification Test / UPSIT) demonstrated that 98% of COVID-I9 patients (n=60) exhibited at least some smell dysfunction. (Moein et aL,2020). A large retrospective cohort of European centers (n=417) found that 86% of patients lost their sense of smell and 89% of patients lost their sense of taste (Lachine et a1.,2020).

It has been demonstrated that loss of smell is one of the most effective and clearest indicators of COVID-19 infection, more than fever and cough (Ashley Yeager, May 12,2020). "In a recent study, Badley and colleagues found that Covid-l9 patients were 2'7 times more likely than others to have lost their sense of smell. But they were only 2.6 times more likely to have fever or chills, suggesting that anosmia produces a clearer signal and may therefore be a better Covid-catching net than “fever" and "There is value in evaluating anosmia screening as a way to identify asymptomatic spreaders," said Badley, the Mayo Clinic researcher " (Sharon Begley, published in FIEALTH on July 2,2020).

Accuracy of the correlation of the lost sense of smell (anosmia) with the diagnosis of positive COVID-19 using Anosmic has been determined based on the scientific evidence obtained from independent scientific publications (Moein et aL,2020, Lachien et al, 2020).

On October 3, 2020 the manufacture submitted a clinical report from a user in India. The report supported the effectiveness of the device for screening purposes.

This product is intended to screen for the potential presence of COVID - 19 by inhalation of the vapors. These vapors can be provided to the subject in two different ways:

1) Using a small inhaler for the nose, and
2) Providing a small amount sprayed on the back of one's hand/Kleenex tissue paper or cotton swab for smelling.

After inhalation, if a distinct smell is not evident, then the person is advised to proceed to COVID-I9 test center or seek additional public health advice.

The ingredients of the vapor comprise of blend of organic natural extracts that are 100% plant based and do not contain any animal, poultry, dairy, nuts, chemicals or CBD. The all-natural ingredients have been selected to be harmless to human health. This device is intended to be used by general public for early detection for loss or reduced sense of smell, as it is one of the eleven symptoms of COVID-I9 identified by Canadian Government (Canada.ca; Coronavirus disease COVID-I9).

3 Conclusion

The device is accurately labelled as a screening device, and recommends appropriate follow up actions if a concern (loss of smell) is noted.

At this time it is not possible to conclusively determine the specificity of the screening tool until further data analysis of COVID-19 negative patients, with anamosia or the time lag in the development of measurable antibody levels.

4 Recommendation

Issue the IO authorization