

Kim, Sabrina

From: Kim, Sabrina
Sent: Monday, May 25, 2020 10:23 AM
To: Gordon2, Travis (HC/SC)
Subject: RE: Guangdog

Thank you!

From: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Sent: Monday, May 25, 2020 10:07 AM
To: Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca>
Subject: RE: Guangdog

Yup, we're on it

From: Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca>
Sent: 2020-05-25 10:06 AM
To: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Subject: RE: Guangdog

Thanks friend. I think your boss was asked about this at OGGO the other day and she said she didn't have the details but that she'd follow up. Just FYI!

From: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Sent: Monday, May 18, 2020 6:32 PM
To: Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca>
Subject: Guangdog

Following the issues raised recently with KN95 masks, MDD reviewed all of the IOs related to KN95s, including the one issued for the Guangdong Golden Leaves N95.

We have contacted the manufacturer to request additional information with regard to any reported incidents.

In the case of this company, we had sufficient evidence on file to support their authorization as the manufacturer had submitted evidence of quality manufacturing and validated test results from independent testing facilities for their authorization. It was tested to GB2626-2006 by the Guangdong Testing Institute of Product Quality Supervision. It is listed as an accredited laboratory in China (CNAS). The device is not listed on the US FDA / CDC website as either accepted or canceled. They may not be selling under the EUA.

In light of media article, we will be contacting our US FDA counterparts to validate if they have in fact revoked their authorization, confirm what actions they may have taken, and ask for any information they have used to make their decision.

We recently sent a letter to this company to request additional information such as marketing history. If necessary, we will contact the company again to request further evidence, as necessary. Any further action necessary will be coordinated with ROEB.

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Travis Gordon
Senior Policy Advisor
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