

Exton, Adam (HC/SC)

From: Gordon2, Travis (HC/SC)
Sent: 2020-07-28 5:12 PM
To: Nowers, Kathryn (HC/SC)
Subject: FW: Swab regulation

From: Wen, Vanessa (HC/SC)
Sent: 2020-05-29 4:12 PM
To: Gordon2, Travis (HC/SC)
Subject: Swab regulation

Here is the response:

Oral/nasal swabs are Class I medical devices. Under normal conditions, they would be subject medical device establishment licensing (ROEB).

During COVID, we are encouraging manufacturers to submit swab applications through the IO pathway - <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/products-authorized-interim-orde.html#t1>

Guidance: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19/guidance-medical-device-applications.html>

From the chart- you'll see we have 2 swabs authorized under the IO