

Belliveau, Sébastien

From: MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>
Sent: May 5, 2020 6:23 AM
To: Belliveau, Sébastien
Subject: RE: Medical Devices Approved - Stats
Attachments: MDEL numbers May 4.docx

Hi Sebas,

These are the ones current to yesterday, attached.

They are all approved under the Interim Order, yes.

Ash

Aisling MacKnight
(613) 327-2803

From: Belliveau, Sébastien <Sebastien.Belliveau@pmo-cpm.gc.ca>
Sent: 2020-05-05 6:22 AM
To: MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>
Subject: Medical Devices Approved - Stats

Hi!

Can you please send me the latest numbers?

Also, can we confirm that those numbers are all under the OIC to expedite approvals?

Thanks!
Sébas

Sébastien Belliveau
Directeur adjoint / Deputy Director
Gestion des enjeux et affaires parlementaires
Issues Management and Parliamentary Affairs
Cabinet du premier ministre / Office of the Prime Minister

HC APPROVALS: May 4

MEDICAL DEVICE ESTABLISHMENT LICENCES (MDELs)

- Total MDELs issued: **787**
- Total MDEL applications being **reviewed**: 70
- Total applications **rejected** based on lack of critical information required to ensure effective oversight of the activity being licensed: 150 (+14).
 - These companies receive an email indicating that the application was incomplete and have been provided with a link to guidance on how to apply.

MEDICAL DEVICES

- Authorized a total of **122 devices**:
 - **15** authorizations for **test kits**.
 - **107** authorizations for **non-diagnostic devices** (masks, gloves, face shields, sterilizers, thermometers, airway management, beds, swabs, isolation kits, ventilators, ventilator accessories, AI for diagnosis, test reagents, swabs, monitors, diabetes management, CPAP helmets, infusion pumps and a thermal camera).
- As of **April 30**, **32** applications for diagnostic devices are **under review**.
- As of **April 30**, **493** applications for **non-diagnostic devices** being **processed**

HAND SANITIZERS AND DISINFECTANTS

- As of **April 30**, Health Canada has authorized **a total of**:
 - **56 disinfectants**
 - **1,651** new hand sanitizer products
 - **1,193** new site licences for over-the-counter (OTC) drugs and natural health products (NHP).
- As of **April 30**, Health Canada's website provides information on
 - **2,082** approved hand sanitizer products and
 - **368** approved hard-surface disinfectant products against COVID-19.