Registrar Corp

U.S. FDA enforcement during COVID-19 is fluid.
This guide was last updated: April 6th, 2020

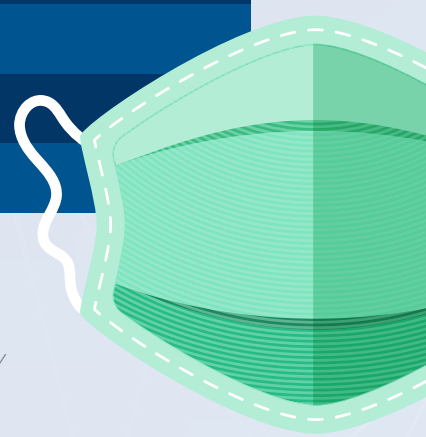
FDA REQUIREMENTS FOR
High Demand COVID-19 Devices

Registrar Corp can answer any questions you may have about product codes and FDA requirements specific to your medical devices.

Masks

The following is not an all inclusive list of FDA product codes.
Click the product codes below for the FDA definition of each device.

Product Code	FDA Registration*	510(k)*	NIOSH Approval**	Prevents Infection	Antiviral or Antimicrobial	Resists Fluids	For General Public Use
NZJ	✓	✓	✓	✓			✓
ONT	✓	✓	✓	✓	✓		
ORW	✓	✓	✓	✓	✓		✓
MSH	✓		✓			✓	
QKR	✓						✓
OUK	✓	✓		✓	✓		
FXX	✓	✓		✓			
OXZ	✓						



** FDA has temporarily waived registration and 510(k) requirements for face masks and CDC-recognized respirators*

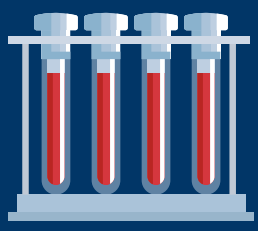
*** N95 respirators must have NIOSH-approval, CDC-recognition, or Emergency Use Authorization (EUA)*

FDA waived certain requirements for:

- Air Purifiers
- Disinfectant Devices
- Face Shields
- Gowns
- Gloves
- Sterilizers
- Thermometers

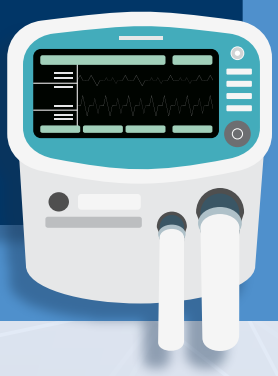
Enforcement Discretion

510(k) or EUA



COVID-19 Test Kits

Ventilators



Per FDA's Enforcement Policy, manufacturers may request EUA to market certain products without a 510(k).

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