

Center for Devices and Radiological Health's Response to COVID-19

TIMELINE: JANUARY 1 — DECEMBER 28, 2020



REGULATORY FLEXIBILITY



Proactively issued policies to provide regulatory flexibility

to address the pandemic

11
EUA TEMPLATES

&

26
GUIDANCE DOCUMENTS

Including policies intended to help:

Car manufacturers making ventilators

Apparel manufacturers making masks

3D printers making ventilator components

EMERGENCY USE AUTHORIZATIONS



608 MEDICAL DEVICES AUTHORIZED UNDER EUAs (ALMOST **10X** THE NUMBER AUTHORIZED IN ALL PRIOR NATIONAL EMERGENCIES)

INCLUDING:

309
TESTS

OF WHICH ARE

235
MOLECULAR

11
ANTIGEN

63
ANTIBODY

TESTS

RECEIVED

1,995
Pre-EUAs

3,521
EUAs

SHORTAGE MITIGATION ACTIVITIES



Outreach to **1,000+** manufacturing sites

ACROSS

12
COUNTRIES

to assess supply chain vulnerabilities

RESULT

Identified potential supply chain issues early and worked to minimize disruptions

PUBLIC HEALTH SERVICE CORPS DEPLOYMENT



61
CDRH Commissioned Corps officers

HAVE BEEN DEPLOYED

90
TIMES

in support of the COVID-19 mission

ENGAGEMENT WITH STAKEHOLDERS



Sent

19M
E-MAILS

to stakeholders on COVID-19 topics

RESPONDED TO:

357,000
E-MAIL & PHONE QUERIES

from patients, health care personnel, industry, & others

HOSTED

53
COVID-RELATED WEBINARS

TOWNHALLS WITH

&

44,000+
PARTICIPANTS