

FDA Immediate in Effect Guidance 2020

“... Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters” may be added without the need for 510k submission

<https://www.fda.gov/media/136318/download>

Page 8

Contains Nonbinding Recommendations

Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)

Contains Nonbinding Recommendations


Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Contains Nonbinding Recommendations

Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

March 2020

 **FDA U.S. FOOD & DRUG ADMINISTRATION** U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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asive Remote Monitoring Devices
Disease 2019 (COVID-19) Public
updated June 2020.

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