HONIGMAN

Diagnostics and Testing

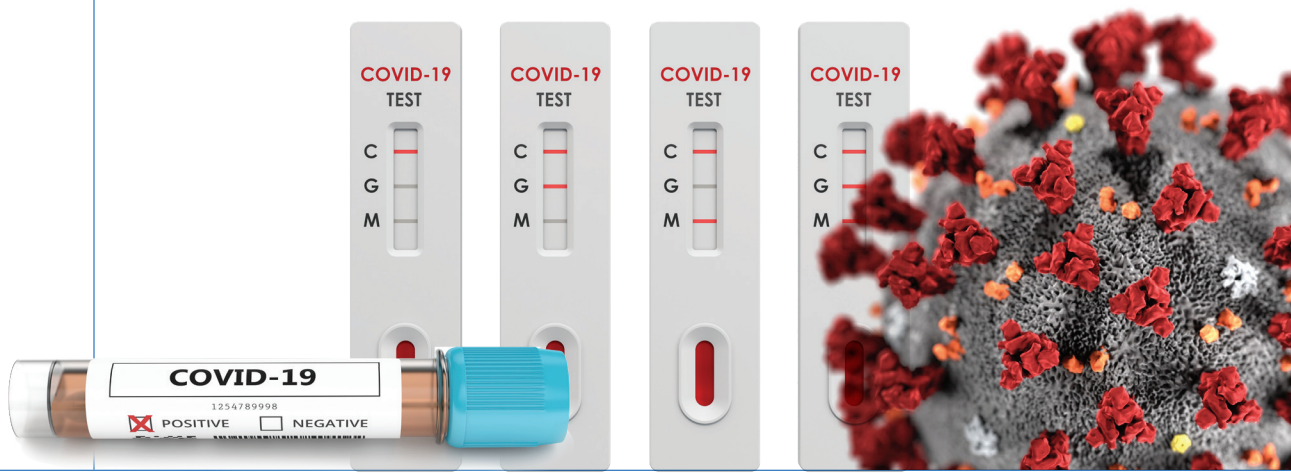
Emergency Use Authorization

Typically, it is unlawful to introduce a medical device into the stream of commerce unless the device has undergone certain regulatory review. Diagnostics fall into the medical device category for regulatory purposes. Generally, medical devices that will be used in humans to treat, prevent, or diagnose disease fall within the jurisdiction of the Food and Drug Administration (FDA). Most diagnostics will require clearance pursuant to a 510(k) filing, which is a submission made to the FDA to demonstrate that the device is substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) which has already been shown to be safe and effective.

Updated Guidance on Testing

In time of emergency, such as with a pandemic, pursuant to Section 564 of the Food Drug and Cosmetic Act ("Act") the FDA can allow devices into the market that: (1) are not approved, (2) have not received clearance for distribution, or (3) have been cleared or approved but not for the newly proposed use during a national emergency pursuant to Section 564 of the Act. In order to invoke Section 564, the Emergency Use Authorization (EUA), the Secretary of HHS must first have declared a national emergency as has happened with this current COVID-19 pandemic.

From time to time, the FDA will issue guidance documents that provide direction to the industry on its current thinking as to certain regulations. On March 12, 2020, the FDA issued an updated guidance on the use of diagnostic testing during the COVID-19 pandemic. The guidance was prompted by the unavailability of COVID-19 testing, the crisis in New York City with COVID-19, and the subsequent memorandum issued by



the President of the United States giving the FDA the authority to do elsewhere what it did in New York, which is to use novel diagnostics which have not gone through the FDA regulatory process.

This March 12, 2020 guidance is a temporary guidance and will be in force through the entirety of the national emergency. This guidance allows for states to authorize laboratory tests developed by high-complexity labs, in lieu of obtaining an EUA or going through the typical FDA regulatory clearance process. The goal was to make testing for COVID-19 more readily available. There are restrictions on the use of these "uncleared" tests including the requirement that states notify the FDA when using tests which are not the subject of an EUA or a 510(k) clearance.

Test Types

Understanding that extraordinary measures are being undertaken to make testing available, the FDA, as noted above, is allowing tests for COVID-19 to enter the market without full regulatory clearance. Currently, there are two types of tests available on the market: one which measures the antibodies demonstrating that the COVID-19 virus was present, or is present (serological), and the other is an antigen testing (the nasal swabs). For the serological testing, the FDA has created a policy during this national emergency that it will not object to the distribution of such tests, provided that the test has been validated; that the FDA has been notified of its existence, validation and the intent to distribute; and the test has a disclaimer that the test has not undergone FDA clearance or review. The submission of an EUA is not required for serological tests. For the antigen testing, a manufacturer must provide validation of the tests through the submission of assays and then submit an EUA request within 15 days of the test's first use. If the EUA is not issued, the manufacturer or distributor must cease distribution and a recall must commence for any tests on the market.

Registration

Manufacturers and distributors of medical devices intended to be used commercially must register, and with such registration they must list the devices they intend to make or distribute. (21 C.F.R. § 807.20 (2020)). However, as is typical, there are exceptions. Domestic distributors which are only obtaining the device domestically (not importing), and are only distributing domestically, do not need to register, list, or pay the registration/listing fee (See § 807.20(c) (3)).

For more information

Jonathan P. O'Brien, Ph.D.
Chair, Intellectual Property Department
jobrien@honigman.com
T: 269.337.7704

Diane J. Romza-Kutz
dromza-kutz@honigman.com
312.701.9325

Kathryn D. Doyle
kdoyle@honigman.com
269.337.7836