Table 14—Heating Mode Test Conditions for Units Having a Variable-Speed Compressor—Continued

<table>
<thead>
<tr>
<th>Test description</th>
<th>Air entering indoor unit temperature (°F)</th>
<th>Air entering outdoor unit temperature (°F)</th>
<th>Compressor speed</th>
<th>Heating air volume rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dry bulb</td>
<td>Wet bulb</td>
<td>Dry bulb</td>
<td>Wet bulb</td>
</tr>
<tr>
<td>H1N test (required, steady).</td>
<td>70</td>
<td>60**(max)**</td>
<td>47</td>
<td>43</td>
</tr>
<tr>
<td>H1C2 test (optional, cyclic).</td>
<td>70</td>
<td>60**(max)**</td>
<td>47</td>
<td>43</td>
</tr>
<tr>
<td>H22 test (optional)</td>
<td>70</td>
<td>60**(max)**</td>
<td>35</td>
<td>33</td>
</tr>
<tr>
<td>H2V test (required)</td>
<td>70</td>
<td>60**(max)**</td>
<td>35</td>
<td>33</td>
</tr>
<tr>
<td>H32 test (required, steady).</td>
<td>70</td>
<td>60**(max)**</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>H42 test (optional, steady).</td>
<td>70</td>
<td>60**(max)**</td>
<td>5</td>
<td>3**(max)**</td>
</tr>
</tbody>
</table>

*Defined in section 3.1.4.5 of this appendix.
**Maintain the airflow nozzle(s) static pressure difference or velocity pressure during an ON period at the same pressure or velocity as measured during the H1 test.
***Defined in section 3.1.4.4 of this appendix.
****Maximum speed that the system controls would operate the compressor in normal operation in 17 °F ambient temperature. The H1 test is not needed if the H1N test uses this same compressor speed.
*****Maximum speed that the system controls would operate the compressor in normal operation in 47 °F ambient temperature.
******Defined in section 3.1.4.6 of this appendix.
*******Maximum speed that the system controls would operate the compressor in normal operation at 5 °F ambient temperature.
isocapnic ventilation device as class II

Upon request, FDA has classified the isocapnic ventilation device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 14, 2019.

FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the isocapnic ventilation device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovative devices.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360c(k) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a


Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 18, 2017, Thornhill Research, Inc. submitted a request for De Novo classification of the ClearMate. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in