FDA Regulatory Process for Premarket [510(k)] Submission: General and Antimicrobial containing Surgical N95 Respirators

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Abstract: The Food and Drug Administration (FDA)/Center for Devices and Radiological Health (CDRH) is responsible for regulating medical devices to ensure that they provide a reasonable assurance of safety and effectiveness and to approve or clear these devices for interstate commerce. FDA categorizes medical devices into three classes based on the regulatory controls to mitigate the risk. A premarket notification [510(k)] is a marketing application submitted to FDA to demonstrate that the medical device described is as safe and as effective or substantially equivalent to a legally marketed device that was or is currently on the US market, or was on the market prior to 1976.

The Food and Drug Administration's (FDA) decision making process for clearing Surgical N95 Respirators is determined by the review of *in vitro* data assessments of substantial equivalence with regards to safety and effectiveness. FDA has previously cleared N95 respirators which contain anti-influenza claims or antibacterial claims that are intended for either health care use or general public use during public health medical emergencies. Before submitting a 510(k) submission for Antimicrobial N95 Respirator, sponsors of the device may utilize the pre-submission process to inquire about the types of data recommended to support the intended claims of the N95 Respirator device.