Validation of 3D-Printed Swabs  
(Class 1 Medical Device)

There are a number of aspects to consider when addressing the appropriateness of a 3D-printed swab for use in the context of COVID-19 testing. Depending on the manufacturer, some of the parts mentioned below might not be necessary. However, according to our experience you should address everything listed in some form.

**Necessary Information**
- Material(s) of construction
- Processing agents used in manufacturing
- Cleaning/disinfecting agents used after manufacturing

**Biocompatibility of Swab to Patient**
- Cytotoxicity test
- Toxicological evaluation for sensitization and irritation based on a knowledge of the materials and process chemicals
  - Not necessary to perform extractable and leachable testing

**Suitability of Swab for Virus Sample Recovery**
- Perform comparison tests for the 3D-printed swab along with approved predicate device swabs which are currently on the market. These tests may include testing patients known to be positive for COVID-19 or possibly using a bench top test designed to simulate the capture of a nasopharyngeal sample using a surrogate virus.
- Using the results of the comparison tests, demonstrate adequate detection and capture of sample for the COVID-19 virus or a comparable simulated virus. Also verify the absence of interference from the 3D-printed swab.

**Microbiological Quality**
- Risk assessment to determine necessary level of microbiological quality
  - Sterility
    - Microbiologically controlled
  - If sterility is indicated, determine sterilization process
    - Might be acceptable to initially use abbreviated sterilization process validation
      - Under emergency use approval (EUA) approach

**Functionality**
- Establish specifications – for example:
  - Angle of flexibility without failure
  - Tensile strength
  - Ability to break the applicator stick at appropriate location
  - Consider using predicate swab
  - Consider simulated use test
  - If sterile swabs, verify functionality after sterilization process

**Packaging**
- Validate packaging - Might be acceptable to initially use abbreviated packaging validation
  - Under EUA approach
- Determine shelflife

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