**Classification of Nail Prosthesis**
**FDA Questions**

**General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee**

**October 26-27, 2022**

1. FDA has identified the following risks to health for a nail prosthesis:

| Identified Risk | Description/Examples |
|---|---|
| Adverse tissue reaction | This can result from use of device materials that are not biocompatible. |
| Discomfort, pain or nail breakage | This can result from the device applying too much pressure on the nail. |
| Nail infection | This can result from inadequate cleansing of the nail before application of the prosthesis or from the introduction of microorganisms to the area once the prosthesis is in place. |

**Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of nail prosthesis under product code "MQZ". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of nail prosthesis.**

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

    - insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, AND

    - if the device is purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

    A device should be Class II if:

    - general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND

    - there is sufficient information to establish special controls to provide such assurance.

    A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
    - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
    - establish special controls to provide such assurance, BUT
        I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
        II. does not present a potential unreasonable risk of illness or injury.

FDA does not believe that special controls will be required for nail protheses under product code "MQZ" and that general controls will be sufficient to provide reasonable assurance of the safety and effectiveness for nail protheses. As such, FDA believes that Class I is the appropriate classification for nail prostheses under product code "MQZ".

**Please discuss whether you agree with FDA's proposed classification of Class I for nail prostheses. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**