Classification of Nail Prosthesis Devices Under Product Code “MQZ”

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Outline

- Device Description
- Indications for Use
- Regulatory History
- Clinical Background
- Literature Review
- Medical Device Reports
- Recall History
- Risks to Health & Mitigations
- Proposed Classification
- FDA Questions

Device Description

- Nail prostheses are intended to temporarily provide structure (e.g., splint, brace) to ingrown or damaged nails to correct or support nail growth. Nail prostheses are constructed out of polymeric and/or metallic materials.
  - On ingrown nails, the device may be used to apply outward pressure on each side of the nail between the nail and the surrounding skin and correct nail over-curvature on ingrown nails (predominantly toenails)
  - On injured or deformed nails, the device may be used as a temporary splint (cover) for nail bed reconstruction for injured or deformed nails (predominantly fingernails). The device is temporarily sutured in place and subsequently removed once the desired natural healing of the nail has taken place.

- Nail prosthesis devices intended to correct ingrown nails may be suitable for home use, while a nail prosthesis device intended for injured or deformed nail bed may be used in surgical settings.

Indications for Use

These devices have been cleared for the following indications for use:

- To correct the shape of overcurved and/or painful nails without operation. To loosen and to give shape to thickened nails, overcurved nails and pincer nails without operation.
- To restrain the ingrown portion of the nail to grow in a forward motion, thus eliminating the ingrown nail.
- Splint for reconstruction in acute nail bed injuries or other deformities of the nail plate.

Regulatory History

- Nail prostheses are pre-amendments, unclassified device type (i.e., have been in commercial distribution prior to May 28, 1976.)
- Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.
- To date, FDA has cleared three 510(k)s under the MQZ product code.

510(k) Number	Trade Name	Sponsor
K850803	Nail Splint	INRO MEDICAL DESIGNS, INC.
K960843	STOP-N-GROW	EUROPEAN TOUCH CO. INC.
K162525	Oniko nail brace	BEGUM SAGLIK HIZMETLERI TIBBI MALZEMELER DANISMANLIK LSTIINRO

Clinical Background

Disease Characteristics

Ingrown toenails

- A common foot condition in people of all ages. The condition may develop in any toenails, but more often in the big toe.
- A nail grows into the skin along the side of the toe or when the skin on one or both sides of a nail grow over the edges of the nail.
- Common symptoms: pain, redness, swelling, and infection.
- Factors lead to ingrown nails: wearing tight shoes, improper grooming and trimming of the nail, trauma, infection or certain medical or congenital conditions.

Trauma to the nail plate and nail bed

- Treatment and healing may be more complicated and may affect both aesthetic appearance and functional performance of the nail.
- Failure to achieve a clean flat nailbed may result in a poorly attached nail, dystrophic nail, split nail, thickened and discolored nail and even a short nail with tissue overgrowth.
- If the nail plate does not grow to the tip of the finger, significant loss of tactile sensation may occur, causing functional debility and compromised quality of life.

Clinical Background

Patient Outcomes

Ingrown nails

- Noticed by the patient at early stage when pain starts.
- The healthcare provider diagnoses an ingrown toenail based on the visual checking on the affected toe, the patient's symptoms, and possible causes.
- Some lab tests such as blood test, may be requested if the doctor think an ingrown toenail has caused other complications.

For nails with traumatic injury

- Specialized care, including first treating the nail bed injury and any associated soft tissue loss, followed by ensuring the proper longitudinal growth of the nail plate across a well healed, vascularized flat nail bed.
- Preparing the nail bed may require dermabrasion, excision of scar tissue and tissue grafting and flaps.
- In both phases of treatment, using a nail prothesis or splint is critical to ensure the best cosmetic and functional outcome.

Clinical Background

Currently Available Treatment

Correction of over-curvature for ingrown nails

- Surgically remove the ingrown portion of the nail.
- Over-the counter products include bandage and gel combinations to soften the nail, and topical products that may soften the nailbed to prevent inward growth of the nail.
- Heal on its own or try home remedies such as soaking feet in warm water or applying petroleum jelly to the over-curved nail.

For nails with traumatic injury

- Surgical repair of the traumatic finger and nailbed.
- Wound care and bandaging.
- Heal on its own.

Literature Review

- A systematic literature review was conducted to gather any published information regarding the safety and effectiveness of nail prostheses under product code “MQZ.”
- Literature searches for nail prosthesis device that correct the ingrown nails were conducted to identify any relevant articles published between May 1, 1976, and April 1, 2022 (first search).
- A supplemental literature search was conducted to identify literature reporting outcomes related to the use of nail prosthesis devices such as the Inro Splint between 1976 to July 2022.
- The searches were limited to human clinical studies with full text available in English language focusing.
- The first search yielded 3 records. The supplemental search for INRO splint yielded one article.
- A total of 4 published literature references, covering 4 studies, were determined to be relevant to the safety and/or effectiveness of nail prostheses.

Literature Review – Safety Assessment

The literature reported on the following adverse events related with the use of nail prosthesis devices:

- Temporary pain with the treatment of nail braces (Wang et al. 2020)
- Nail brace dislocations (Wang et al. 2020)
- Minor nail infections (Kim et al, 2009; Ogunro et al. 1989)

Literature Review – Effectiveness Assessment

Ingrown nails: 4-8% of patients experienced a recurrence in nail deformity and nearly all patients reported pain relief within one day (Wang et al. 2020; Kim et al, 2009)

Nails with traumatic injury: Nail regrowth was observed In 16 nails out of 18 fingers treated with the INRO surgical nail splint(Ogunro et al. 1989)

Literature Review – Summation

- The literature search between years 1976 to 2022 yielded a total of four literature references that were applicable to evaluating the safety and effectiveness of nail prostheses.

- The quality of evidence in the reviewed studies was low with very limited generalizability.

Medical Device Reports

- Medical Device Reporting (MDR): the mechanism for the FDA to receive significant medical device adverse events from:
  - mandatory reporters (manufacturers, importers and user facilities)
  - voluntary reporters (health care professionals, patients, consumers)

Medical Device Reports

- MDR reports can be used effectively to:
  - Establish a qualitative snapshot of adverse events for a specific device or device type
  - Detect actual or potential device problems used in a “real world” setting/environment, including:
    - rare, serious, or unexpected adverse events
    - adverse events that occur during long-term device use
    - adverse events associated with vulnerable populations
    - off-label use
    - user error

Medical Device Reports

- Limitations
  - Under reporting of events
  - Potential submission of incomplete, inaccurate, untimely, unverified, or biased data
  - Incidence or prevalence of an event cannot be determined from this reporting system alone
  - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report
  - MAUDE data does not represent all known safety information for a reported medical device

Medical Device Reports

- MAUDE (Manufacturer And User Facility Device Experience) Database reviewed for product code “MQZ” with no date limitation on May 24, 2022.

- No relevant MDRs for nail prosthesis devices were identified.

Recall History

- The Medical Device Recall database contains medical device recalls classified since November 2002.
- Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA.
- The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated.
- FDA recall classification (resulting in the posting date) may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall.

Recall History

- Medical Device Recall database was reviewed for product code “MQZ” with no date limitation on August 18, 2022.

- No relevant recalls for nail prostheses were identified.

Risks and Examples

Identified Risk	Description/Examples
Adverse Tissue Reaction	This can result from the 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.

We believe general controls are sufficient to mitigate these risks.

Proposed Classification

878.3560 Nail prosthesis.

(a) Identification.

A nail prosthesis is intended to temporarily provide structure to ingrown or damaged nails to correct or support nail growth. A nail prosthesis device intended for ingrown nails helps to correct nail over-curvature. A nail prosthesis device intended for injured or deformed nails, such as after traumatic injury, may serve as a temporary splint to physically cover and protect the injured or damaged nailbed during the healing process. A nail prosthesis is not intended for used on infected nails.

(b) *Classification.*

Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

U.S. FOOD & DRUG ADMINISTRATION

Thank You

Questions to Panel – Nail Prostheses, MQZ

Meixia Bi, Lead Reviewer, OHT4

Question 1 to Panel

FDA has identified the following risks to health for nail prostheses:

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 prostheses 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 prostheses.

Question 2 to Panel

- 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
  - the device is 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, 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.

Question 2 to Panel

- 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
      - 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
      - does not present a potential unreasonable risk of illness or injury.

Question 2 to Panel

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

If you believe that Class II is appropriate for nail prostheses, please discuss appropriate controls that would be necessary to mitigate the risks to health for these devices.

End of Panel Questions for Product Code “MQZ”

Meixia Bi, Lead Reviewer, OHT4