

『개인맞춤형 의료기기(PMD) 실무그룹 업무 진행 현황』

2022.9.2



식품의약품안전처

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- Personalized Medical Devices-Production Validation

2. 기존 가이드라인 개정

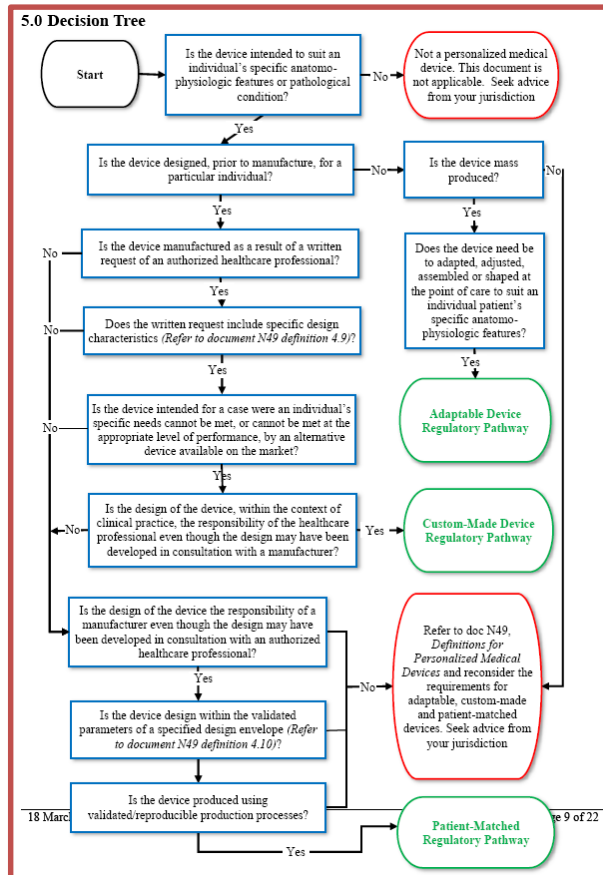
- Personalized Medical Devices-Regulatory Pathways(N58)

3. 향후 계획



✓ 2020년 환자 맞춤형 의료기기 규제 경로 가이드라인 제정(20.3.18)

* Personalized Medical Device- Regulatory Pathways(N58)



JOURNAL OF 3D PRINTING IN MEDICINE, VOL. 5, NO. 1 | PERSPECTIVE

The role of 3D printing in the fight against COVID-19 outbreak

Payar Radfar[‡], Sajad Razavi Bazaz[‡] , Fateme Mirakhorli & Majid Ebrahimi Warkiani

Published Online: 5 May 2021 | <https://doi.org/10.2217/3dp-2020-0028>

3D Printing Can Strengthen America's Medical Supply Chain

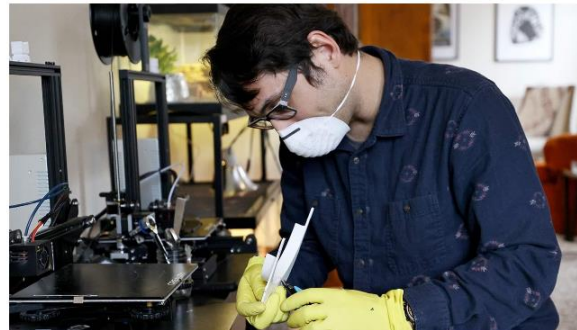
Health care experts share lessons from the COVID-19 pandemic

ARTICLE | July 27, 2022 | By: Zahra Younoszai | Read time: 4 min

Projects: Health Care Products

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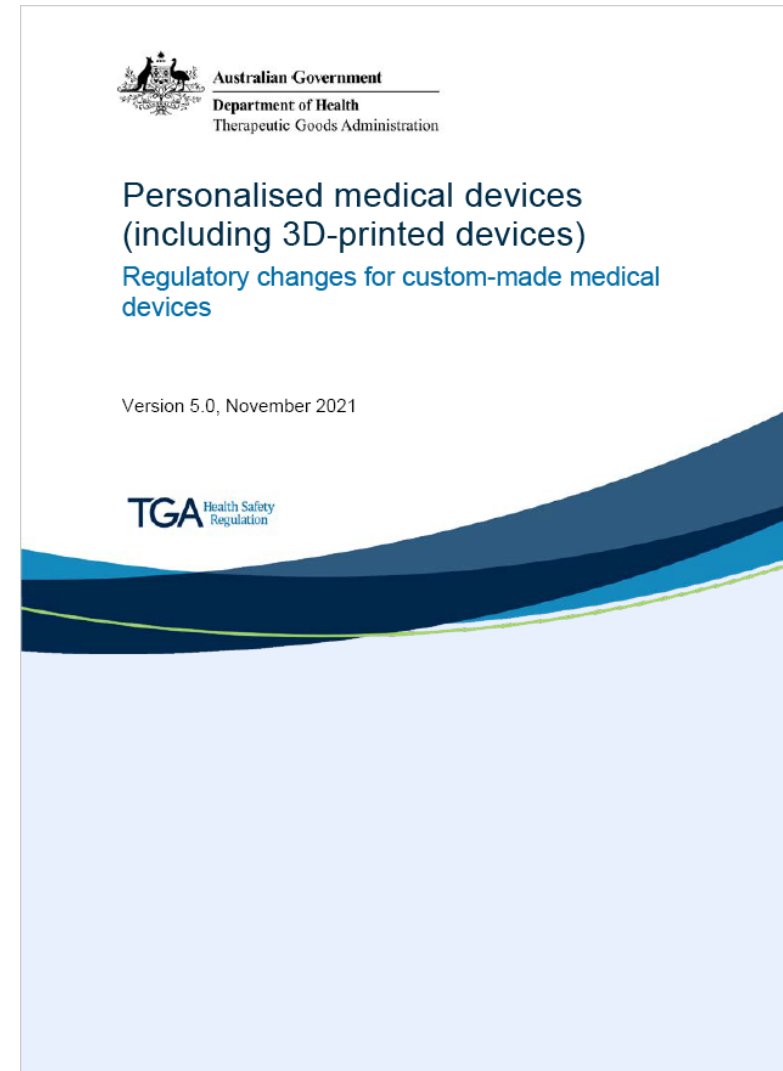
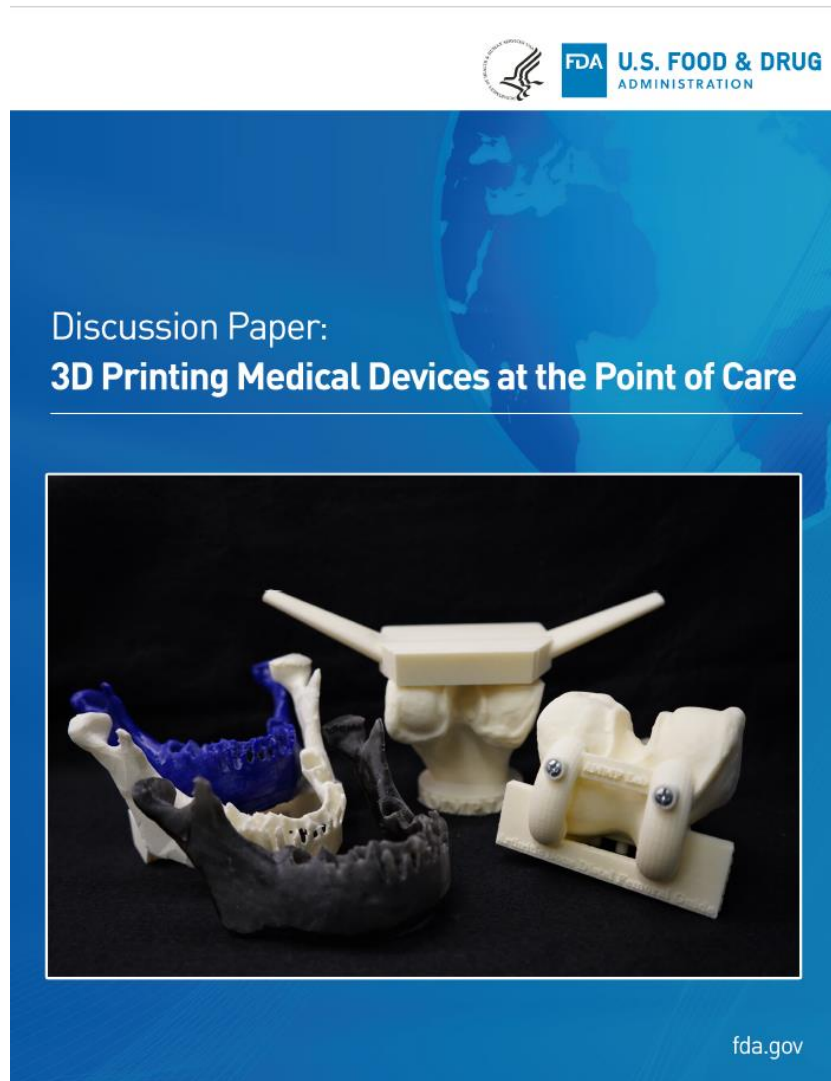


ISSUE BRIEF | July 27, 2022

FDA's Regulatory Framework for



배경 및 현황- 참고 가이드라인





PMD- Production Verification and Validation

✓ 신규 가이드라인 제정 작업 진행 중(21년 ~ 진행중)

* Personalized Medical Device – Production Verification and Validation

- Technical guidance on validation aspects of specified design envelope and medical device production system

* 가이드라인 목적(Purpose)

- To provide harmonized **recommendations for verification and validation aspects** of patient mated medical devices **and medical device production system(MDPS)**

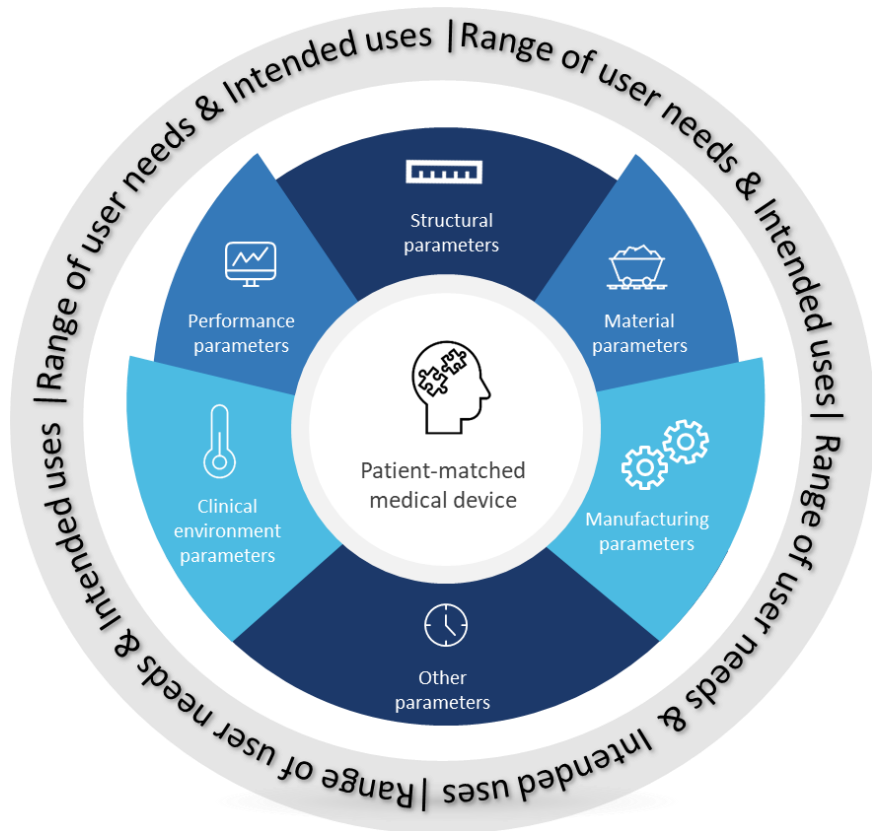
* 가이드라인 범위(Scope)

- Patient-matched medical device
- Medical Device Production System
- not apply to IVD
- not apply to medical device – incorporating materials of biological origin/medicinal product/drug/active deivce, etc.



PMD- Production Verification and Validation

✓ Specified Design Envelope for patient matched medical device



- ✓ Structural parameter
- ✓ Material parameter
- ✓ Manufacturing parameter
- ✓ Clinical environment parameter
- ✓ Performance parameter
- ✓ Miscellaneous parameter

✓ Validation 외 추가 고려사항

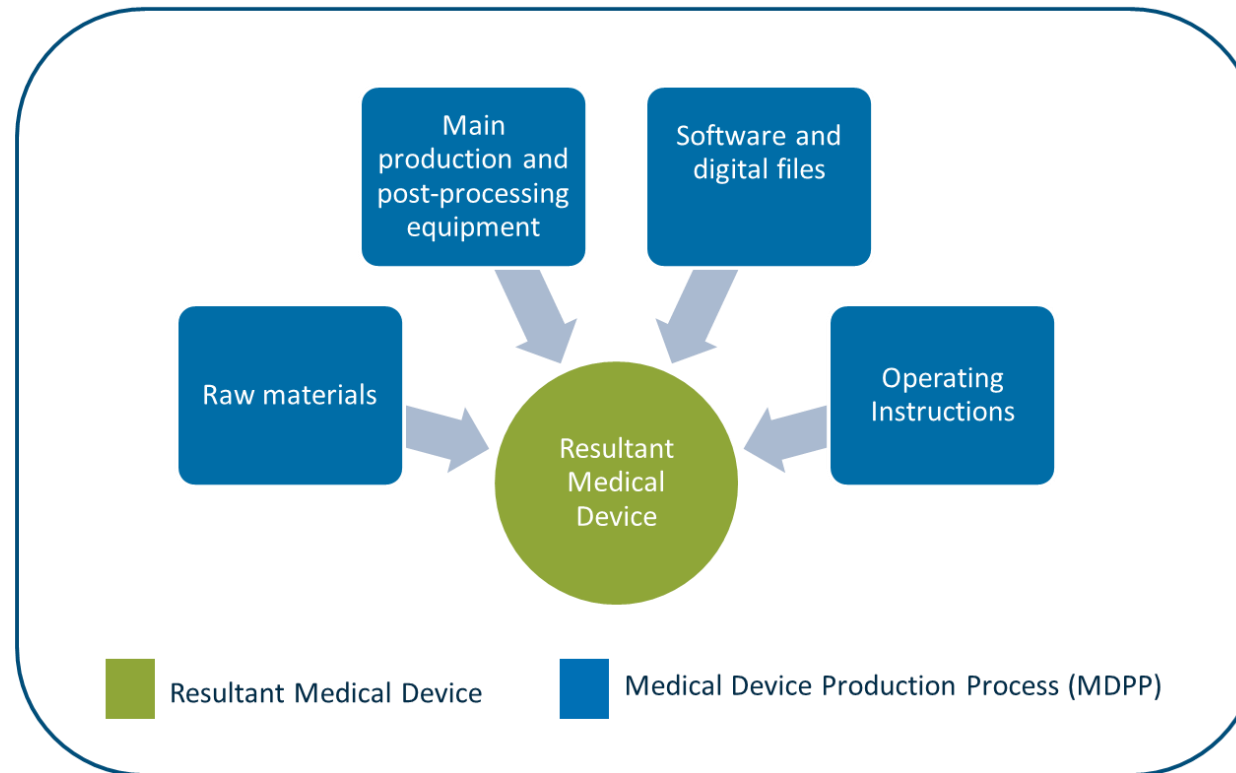
- Use of imaging data for patient matching
- Clinical evaluation
- labelling



PMD- Production Verification and Validation

- ✓ Validation aspects of medical device production system

Medical Device Production System





PMD- Production Verification and Validation

✓ **Medical device production system = MDPP + RMD**

* **MDPP – Medical device production process**

- raw materials/ main production/ post processing equipment/ software/ digital files/
operating instructions

* **RMD – Resultant medical device**

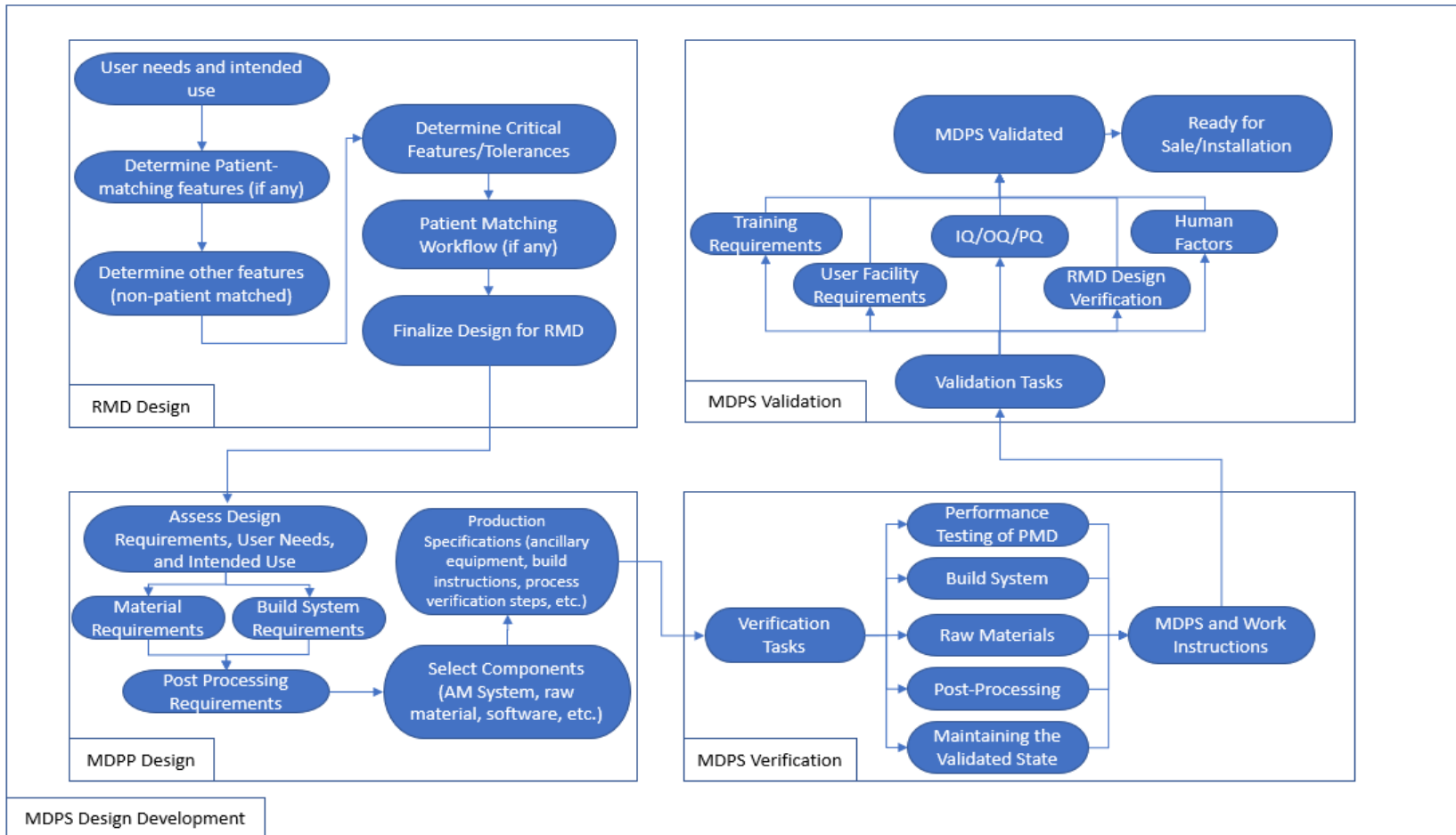
- specific medical device that the MDPP produces using the operating instructions supplied by the MDPS manufacturer

→ MDPS의 classification, labelling 등 추가 개념 도입



PMD- Production Verification and Validation

✓ Design development of MDPS



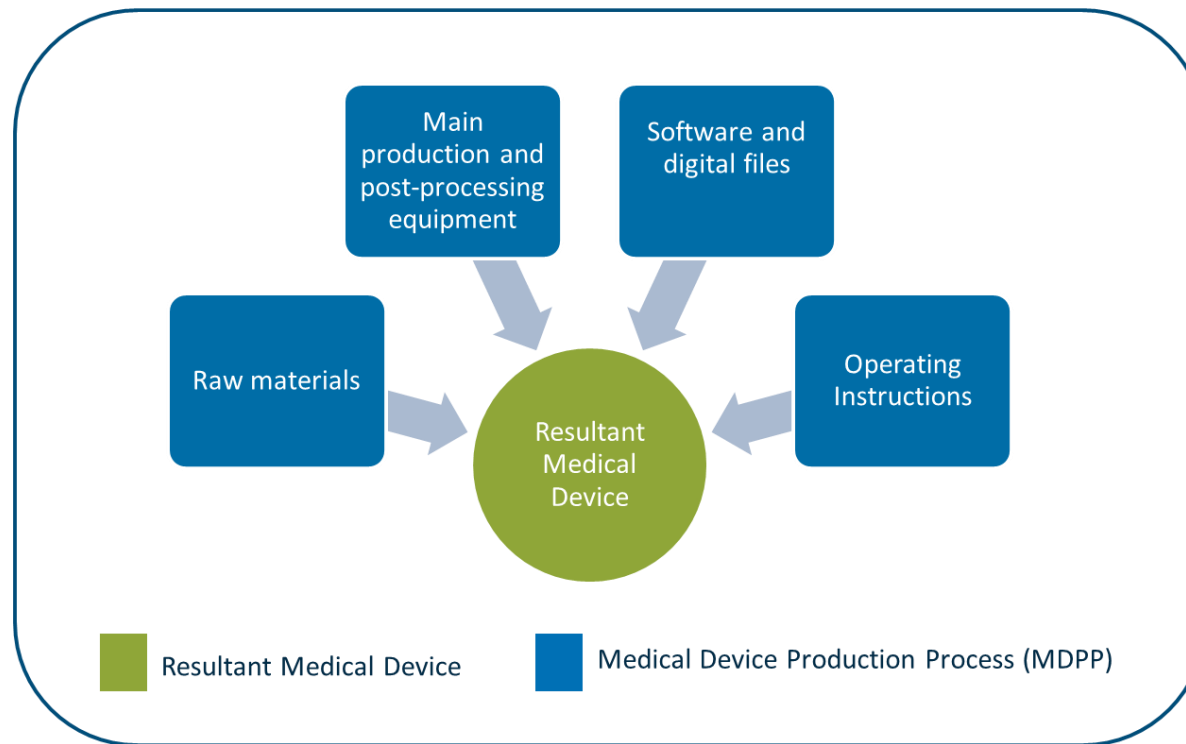


PMD- Regulatory Pathways(N58)

✓ 가이드라인 주요 개정 사항

* MDPS 개념 추가

Medical Device Production System





가이드라인 제개정 향후 계획

- ✓ Deep dive meeting : 5th Aug. ~ 10th Aug.
- ✓ Final version Review (~End of Aug)
- ✓ Public consultation (60 days or 90 days)