

MEDENTIKA®

FDA | PnP
COMPLIANCE



The key benefit of the PnP workflow is that labs can avoid implementing their own costly and time-consuming Quality Management System (QMS) by following Medentika's accredited process.

The validated workflow covers the entire digital process for creating a custom abutment, from scanning to final bonding:

Validated components: Labs must use FDA-accredited Medentika components, including titanium bases, PreFace blanks, and approved digital libraries.

Approved equipment: The process is compatible with a wide and growing ecosystem of validated scanners, CAD/CAM software (like 3Shape and exocad), and milling machines (like Versamill).

FDA clearance: By using the Medentika PnP workflow, labs are covered by Medentika's existing FDA clearance for these components and procedures. This results in an FDA-cleared final medical device.

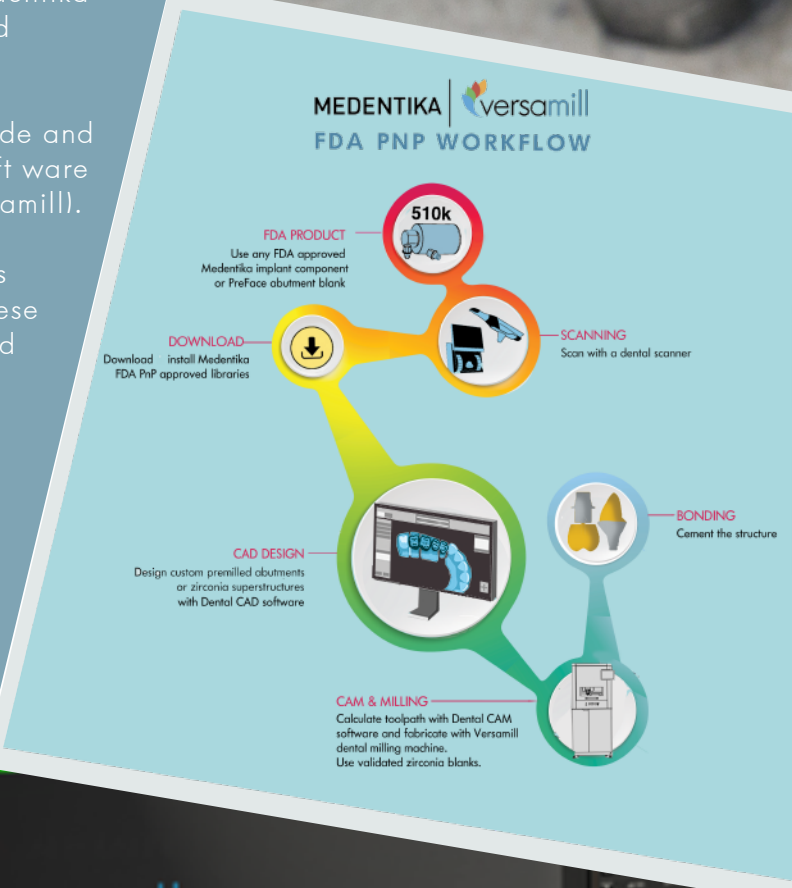
Benefits for dental labs and clinicians

Simplified compliance: The primary is making FDA compliance for custom abutments simple and accessible.

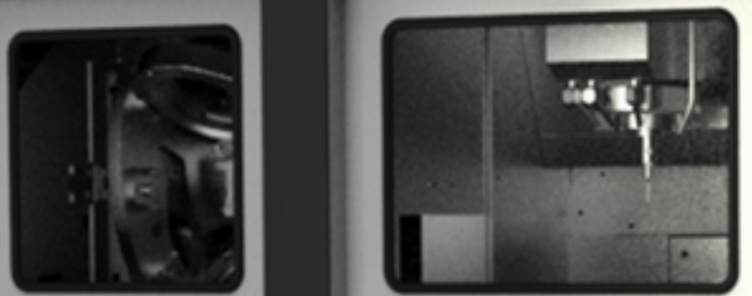
Increased control and efficiency: By milling abutments in-house, labs gain more control over the production process, potentially improving turnaround times and reducing costs.

Quality and predictability: Using a validated and proven workflow ensures predictable and high-quality results.

Flexibility: Labs can integrate their preferred compatible hardware



versamill
5X500L



Dental SOLUTIONS



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