

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K081520

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
Sensitouch Plate Viewer, N50531

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

No changes were made to the Indication/Intended Use.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
This change was for the addition of the Vizion plate viewer to the Sensititre MIC and Breakpoint Susceptibility system. The fundamental Scientific Technology of the device did not change.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

Table1. Feature Comparison of Vizion with the SensiTouch instrument				
FEATURE	SENSITOUCH	VIZION	EQUIVALENT	COMMENTS
CORE SYSTEM:				
TECHNOLOGY	The panel image is displayed on a mirror with an LCD overlay over the panel image	The panel image is displayed on a touch screen directly from a video camera	Yes	Equivalence shown by in house performance testing and preliminary clinical data.
RESULTS ENTRY	MIC results selected by the user	MIC results selected by the user	Yes	User selects the result
INSTRUMENT DESIGN:				
PANEL ENTRY	The panel is entered into the instrument via a manually operated drawer	The panel is entered into the instrument via a manually operated drawer	Yes	Entry exactly the same on both instruments.
LIGHTING	The Sensitouch has set light settings	The Vizion has variable light settings controlled by the user	Yes	The light adjustment allows much better control for the user
WORKFLOW	Panel results are selected by the user and recorded via a touch pad connected to a PC with Swin software,	Panel results are selected by the user and recorded via a touch screen connected to a PC, with Swin software.	Yes	Workflow is the same as the Sensitouch
CIRCUIT BOARDS	Near Obsolescence	Upgraded and to meet all current regulations	Changed to meet current manufacturing requirements	PC boards upgraded to state-of-the-art-technology.
INTERFACE TO PC	RS232 cable connection	USB connection	Changed to use current technology	RS232 is becoming obsolete.
USER INTERFACE PC				
OPERATING SYSTEM	WINDOWS	WINDOWS	No change	Same software used for both

				instruments
HARDWARE SPECIFICATION	WINDOWS compatible PC	WINDOWS compatible PC	No change	Same software used for both instruments
DATA MANAGEMENT	Done at the PC including all reporting	Done at the PC including all reporting	No change	Same software used for both instruments
OTHER SYSTEM FEATURES				
AGENCY COMPLIANCE	CSA (Including USA), CE	CSA (Including USA), CE	No change	

5. A **Design Control Activities Summary** which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis;

The manufacturer submitted a Risk Analysis method based on potential hazards that could occur with use of the device. Recommended mitigations were identified for each hazard followed by statements of residual risk after implementation of mitigations.

- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The verification and validation activities were submitted and, in general, are satisfactory. The sponsor submitted MIC results comparing the performance of the Vizion to the Sensitouch plate viewer from in-house testing as well as three external sites to demonstrate that the modification did not impact the performance of the device. The sponsor stated that Risk # 19 (Endpoint Read Differences) studies were not completed for the verification and validation activities of the Vizion reader. Because this information is critical to determine if there is a significant risk associated with adding a new reader, the sponsor was asked to perform a study with 3 individuals reading the same plates but blinded to the light settings used by the other individuals. The sponsor performed the study in-house and the results were satisfactory. We performed an interactive exchange to agree upon the content of the Vizion User Manual. In addition the SWIN software used by the reader was reviewed.

- c) A declaration of conformity with design controls. The declaration of conformity should include:
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The declaration of conformity with design controls was submitted and is satisfactory.

6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement** and the **Indications** for

Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.