K960712

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. The submitter of this premarket notification is

Pamela S. Angell
Binax, Inc.
217 Read Street
Portland, Maine 04103

The contact person is Pamela S. Angell.

2. The name of the device is *Binax Strep A Test*, also known as Strep A ICT. The classification name per Section 866.3740 is "Streptococcus Spp. Serological Reagents."

3. The device is substantially equivalent to Quidel QuickVue In-Line One-Step (510(k) no. K934484) and Abbott TestPack Plus (510(k) nos. K901274 & K922345) Strep A Tests.

4. The *Binax Strep A Test* is an immunochromatographic membrane assay to detect *Streptococcus pyogenes* Group A antigen from throat swabs. A test strip, containing gold-conjugated and immobilized anti-Strep A antibodies, and a swab well are mounted on opposite sides of a cardboard, book-shaped hinged test device. A throat swab is inserted into the swab well, extraction reagents are added from dropper bottles, the swab is rotated three times, and following a 1 minute incubation, the test device is closed. Extracted antigen captured by immobilized anti-Strep A antibody reacts to bind the visualizing gold-conjugate. There are no transferring steps, the sample is contained, and results are available within 6 minutes.

5. The *Binax Strep A Test* is intended for *in vitro* diagnostic use in clinical and physician office laboratories to qualitatively detect the presence of *Streptococcus pyogenes* Group A antigen from throat swabs. The indication statements are the same as those made for the predicate devices.

6. The technological characteristics of the *Binax Strep A Test* are the same or similar to those found with the predicate devices. All tests utilize antibodies specific for *Streptococcus pyogenes* Group A antigen for capture and conjugated antibody for detection. Both the *Binax Strep A Test* and the Quidel QuickVue use an on-board or in-the-device extraction of antigen. Abbott TestPack Plus requires a separate extraction step.

7. Test sensitivity and specificity were determined by testing throat swabs collected from 81 physician office patients in both the Binax test and in culture (page 35). To further demonstrate Binax test specificity, 20 culture negative samples collected

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from subjects who had just consumed 1 of 2 commercially available sore throat medications (page 59) were tested in the Binax test.

Inter- and intra-site reproducibility of the Binax test was examined when 6 operators of varied educational levels each tested 60 blind coded sample swabs (page 50).

25 organisms found primarily in the throat, oropharynx, mucous membranes or respiratory tract were tested for cross-reactivity in the Binax test at 10^7 organisms per test (page 56). A mucoid Streptococcus A strain was tested at 10^5 organisms per test (page 56).

Finally, the ability of the *Binax Strep A Test* control to indicate test failure was evaluated when each of 3 operators ran 20 kit controls in a panel of 20 devices, 8 of which had been rendered inoperative. The number of defective devices and the defect itself were not apparent to the operator (page 62).

Preliminary stability studies of positive and negative control swabs and of device and extraction reagents are ongoing at various temperatures (page 67).

8. The *Binax Strep A Test* is substantially equivalent to both predicates when compared to the "Gold Standard" - culture. Binax, Quidel and Abbott test sensitivities, when calculated against sheep blood agar confirmed positive specimens, are substantially equivalent. Binax test sensitivity is 80%, while Abbott and Quidel are both 90% (page 12).

   A direct comparison of Binax and predicate test sensitivities performed at Binax further substantiates equivalence. The Binax, Abbott and Quidel tests detected 3 x 10^5 organisms per test 100%, 96% and 95% of the time, respectively. The Binax test detected 1 x 10^5 organisms per test 84% of the time while the Abbott test detected this concentration of organism 89% and Quidel 39% of the time (page 66).

   Binax test specificity is 97% vs. Quidel specificity of 96% and Abbott specificity of 95% (page 12).

Signed Pamela S Angell
Pamela S. Angell

Date 2/16/96