SECTION VI

AUG 14 1997

510(k) Summary

K971953

Tomey ConfoScan Confocal Microscope

Common/Classification Name: Microscope, Ophthalmic, 21 CFR 886.1850

Applicant:

Tomey Corporation
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Attn: Mr. Susumu Nozawa (Manager / Regulatory)
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Correspondent:

Tomey Corporation (USA)
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Contact: Dave Maclellan (Engineer)

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Prepared: April 1, 1996

A. LEGALLY MARKETED PREDICATE DEVICES

Tandem Scanning Confocal Microscope as manufactured by Tandem Scanning Corporation, Reston VA (as cleared in K912514)

Tomey EM-100 Specular Microscope by Tomey Corporation, Cambridge, MA (as cleared in K944910).

Tomey Video Vision Analyzer, VRB 100 by Tomey Corporation, Cambridge, MA (as cleared in K945959).

B. DEVICE DESCRIPTION

The Tomey "**ConfoScan**" Confocal Microscope is a scanning slit microscope system that is used to carry out a visualization of the cell layers of the anterior parts of the eye. The prime attributes of a Confocal Microscope include both improved contrast and spatial resolution over more conventional microscopy. The improved image rendition is accomplished in the Tomey "**ConfoScan**" Confocal Microscope by the introduction conjugate scanning slits into the viewing and illuminating light paths of the microscope. By illuminating and viewing an object through restricted apertures, it is possible to eliminate the contributions of scattered light from other regions in the object plane that can degrade contrast and spatial resolution.

C. INTENDED USE

The Tomey "**ConfoScan**" Confocal Microscope is intended for use in carrying out a visualization of the cell layers of the anterior parts of the eye.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Tomey Corporation** device has the *same* intended use and target population as the predicate devices, and has *equivalent effectiveness* for its intended use. A table of comparison of the **ConfoScan** system to the predicate devices is presented in **Table 1**.

TABLE 1
Side-by-Side Comparison with Predicate Devices

Characteristic	Tomey ConfoScan	Tandem Scanning	Tomey Specular Microscope	Tomey ViVA
Ophthalmonic Microscope	Yes	Yes	Yes	No
Cornea Contact	Yes	Yes	Yes	No
Floating Objective Lens	Yes	Unknown	No	NA
Working distance	0-10 mm	0-8 mm	0-1.3 mm	100+ cm
Type Scanning Aperture	Slit	Nipkow Disk	NA	NA
Aperture Light Budget	3%	0.25-1%	NA	NA
Light Source	100 W Halogen	100 W Hg Arc	IR	IR
Objective Lens	Achroplan with Floating Mount	Convex Applanating Dipping Cone	Dipping Cone with Floating Mount	NA
Depth Resolution	1 micron	< 1 micron	NA	NA
Horizontal Resolution	10 microns	6 micron	NA	NA
Pre Sterilized	No	No	No	NA

E. NON-CLINICAL TESTING

This section summarizes the performance testing that **Tomey Corporation** carried out on the Tomey **ConfoScan** system. This testing addressed the following issues:

1. Elution testing

The **ConfoScan** passed the Elution test performed according to the requirements of the Ministry of Health and Welfare in Japan.

2. Sterilization

The **ConfoScan** objective lens is intended to be disinfected by the end user employing procedures recommended in the instruction manual.

4. Biocompatibility

The biocompatibility issues for the **ConfoScan** system are identical to those of the many other ophthalmic microscopes employing short focal length immersion lenses.

5. Electrical and Thermal Safety

The ConfoScan system has been certified for Electrical and Thermal safety by the JQA (Japan Quality Assurance Organization).

F. CONCLUSIONS

Tomey Corporation has demonstrated that its evaluation of the **ConfoScan** system and its review of the literature shows equivalent safety and effectiveness with respect to performance, biocompatibility issues, and comfort and corneal surface damage, although no specific claim for these attributes is being made.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 1997

Mr. Dave MacLellan
Engineer
Tomey Corporation USA
325 Vassar Street
Cambridge, MA 02139

Re: K971953
Trade Name: Tomey ConfoScan
Confocal Microscope
Regulatory Class: II
Product Code: 86 HJO
Dated: April 15, 1997
Received: May 28, 1997

Dear Mr. MacLellan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS)inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971953

Device Name: ConfoScan

Indications for Use:

The Tomey "ConfoScan" Confocal Microscope is intended for use as a diagnostic tool for looking at the cell layers of the anterior parts of the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Evanette Y. Dean
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971953